NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS

Indian Council of Medical Research(ICMR)

(formerly Tuberculosis Research Centre)

Department of Health Research, Ministry of Health and Family Welfare

Govt of India

Mayor Sathyamoorthy Road ,Chetpet ,Chennai- 600031

TENDER NOTICE – AUTOMATION OF BACTERIOLOGY LABORATORY

Sealed tenders in **two bid system** are invited up to 3**.00pm** on **29.11.2013** from reputed, experienced and resourceful software development agencies for supply, installation and operationalisation of the following work at this institute, on **turn-key** basis.

- Name of the work: **Automation of Bacteriology Laboratory at NIRT, Chennai**.
- Issue of Tender Forms: **31.10.2013** to **28.11.2013, 12.00 Noon.**
- Pre-Bid Meeting: **22.11.2013, 11.00AM at NIRT, Chennai**.
- Receipt of Bids:**29.11.2013 at 3.00PM**
- Opening of Technical Bid:**29.11.2013 at 3.30 PM**
- Earnest Money Deposit **(EMD) Rs.50,000/- (Rupees Fifty Thousand only).** In case the bidder is exempted from submitting the EMD, they should submit relevant supporting document along with the technical bid.

Tender forms containing detailed specifications and terms and conditions can be obtained from the Administrative officer against payment of Rs.1000/-(Rupees One Thousand only) in Cash/MO/DD up to 3.00 pm on all working days from 31.10.2013 to 28.11.2013.

The Tender forms may also be downloaded from our website **www.nirt.res.in/ www.icmr.nic.in.** In this case, the bidder should submit a DD for Rs.1000/- along with bid.

Note: Changes if any will be uploaded on to the website as corrigendum. Any typographical / printing error may be regretted

DIRECTOR

NIRT

SECTION 1 : INVITATION FOR BIDS (IFB)

1.Scope of Work

The scope of work consists of Development, Supply, Installation, Commissioning and providing handholding support for one year on turn- key basis of the Bacteriology Laboratory Automation System **in NIRT, Chennai** as per details given in **Annexure A**.

2.Eligibilty Criteria

2.1. Should be a resourceful, registered software development agency giving an Undertaking, in original, clearly stating their capacity to develop the system with technology and products updates and extend full support during the entire warranty period. In absence of such undertaking, the Bid is liable to be rejected.

2.2. Should have an average annual turnover of Rs. 1.00 Crore (Rs. One Crore) during last three years. Enclose the copy of audited Annual Turnover Certificate. In absence of such certificate, the Bid is liable to be rejected.

2.3. Should preferably have its local support office in Chennai. Give complete details, if office already exists. If not, explain how the bidder proposes to provide the hand-holding support at site.

2.4. Should have successfully completed two similar works of minimum value of not less than Rs. 10,00,000/- (Rs 10 lakhs) each during the last three years. Enclose the copies of work orders (self attested) along with their satisfactory work completion certificates / reports if the work is completed or copies of work orders if the work is in progress. In absence of supporting documents the Bid is liable to be rejected.

2.5. Should be having all the necessary registrations (as per Pre-Qualification details asked in enclosed Performa in Annexure C) like VAT, Service Tax, TIN, PAN, etc. Enclose proof thereof. In absence of supporting documents, the Bid is liable to be rejected

Before submitting the tender, please verify the eligibility criteria and also ensure fulfilling all the terms and conditions.

3. **For any technical clarifications please contact** (preferably by e-mail):

Director
NIRT(National Institute for Research in Tuberculosis)
Mayor Sathiyamoorthy Road
Chetpet,Chennai 600031,India
email: soumyas@nirt.res.in

4. Bid Submission :

The proposals shall be submitted in Two Bid system, both to be sealed separately - i.e Part I (Technical Bid) and

Part II (Price Bid) in TWO separate sealed envelopes. Both the bids along with the EMD, and non-refundable tender fee (in case of tender forms downloaded from web-site) shall be enclosed in another sealed envelope super scribing:

Sub : Tender for "Development, Supply, Installation and Commissioning and handholding support for one year on turn- key basis of Bacteriology Laboratory Automation System".
Tender Number :
Due Date and Time :

4.1 **Part – I (Technical Bid)** shall contain :

- **Non-Refundable Tender fee** of Rs. 1000/- (Rs. One Thousand Only) in the form of DD / Pay Order favoring NIRT payable at Chennai, in case the tender document is down loaded from the website. Offers without Tender Fee, on tender forms downloaded from website, shall be rejected outright.

- **Refundable Earnest Money Deposit (EMD)** of Rs. 50,000/- (Rs. Fifty Thousand only) in the form of DD / Pay Order favoring NIRT payable at Chennai. Offers without EMD shall be rejected outright.

- **Technical proposal** with full details along with relevant supporting technical literature and description of hardware, software and interconnections proposed to be implemented by the firm, the detailed plan for providing development, installation and warranty services at site to enable NIRT do the technical assessment of the proposal in format given in **Annexure B**.

- **An Undertaking**, as stated as Clause No. 2.1 (Eligibility Criteria) as above, in the letter head of the company, by an authorized signatory affixing his seal.

- Prequalification Criteria as per **Annexure C** along with all the supporting documents.

- If the bidder chooses to use downloaded tender document then they have to submit an undertaking stating that they have not made any amendments / changes in the original tender document. In absence of such undertaking the tender filled in with down-loaded forms is liable to be rejected.

- Any other documents apart from Price Bid shall be enclosed in the Technical Bid.

If the Technical Bid contains any price information the bid is liable to be rejected.

4.2 Part – II (Price Bid) shall contain Only Price Schedule completed in all respects in the enclosed format as per **Annexure – D** with proper seal and signature of the authorized person. Prices should be given in INR in both figures and words. There should not be any cutting or overwriting while filing the price schedule. In case of any ambiguity the entire tender is liable to be rejected.

5. Opening of Technical bid

The technical bid alone will be opened on **29/11/2013 at 15:30**. Interested bidders may attend the technical bid opening as per schedule. Price bid of only technically qualified bidders will be opened at the time and date to be informed later. The outer cover in which these sealed covers (i.e **Part I & II**) are to be placed should be addressed and reached to the

Director
National Institute for Research and Tuberculosis(NiRT)
Mayor Sathiyamoorthy Road
Chetpet, Chennai – 600031
India

Latest by 15:30 hours (3:30 PM) on 29/11/2013

6.Technical Evaluation

6.1 Evaluation Process

The technical bids would be evaluated by a Technical Committee. If required, short listed vendor may be asked to give presentation in front of this committee in 3-4 days notice, at their own expense, on their proposed solution. They are expected to reply to all the queries by the committee during the presentation. This presentation would be part of technical evaluation process.

If a bid is not responsive or not fulfilling all the conditions of the tender or not meeting Technical Specifications and Qualification Requirement, it will be rejected by the committee and may not subsequently be made responsive by correction of the non-conformity.

Proposal will be reviewed to assess compliance with the requirements set out on this tender document. Proposals that do not fully comply with the minimum requirements will be rejected without further consideration.

6.2 The Evaluation Criteria

The bids will be technically evaluated on a scale of 0-100 based on the criteria and marks for each as given in table I(a) and I(b).

Table I(a) : Point System for Evaluation of Technical Proposal – Part A – Organizational Capability

S. No	Criteria	Max. Marks	Response Expected	Evaluation Criteria
1	Number of years of experience	5	Submission of Certificate of incorporation & Certificate of Commencement of Business and Certificate of first Project executed by the organization.	0- 1 years– no marks. 1-2 years – 1 mark 2-5 years – 2 marks 5-9 years – 4 marks More than 10 years-5 marks
2	Quality Certification	5	Submission of valid and relevant Quality Certificates.	No Certificates - 0 ISO Certificate - 2 CMM Level 3 – 3 CMM level 4 - 4 CMM Level 5 - 5
3	Presence in Chennai	10	Submission of valid and relevant documents giving address of the unit in Chennai with phone number.	No Presence - 0 Service centre - 2 Branch Office – 8 Head Office - 10
4	Human Resources Strength	5	Submission of a Certificate from Company Secretary showing Experience of bidder and volume of manpower in the field of IT.	Total Employees: < 10 →0 marks Between 10 and 20 → 1 marks Between 20 and 30 → 2 marks Between 30 and 50 → 3 marks Between 50 and 70 → 4 marks > 70 → 5 marks
5	Project Experience in health related projects	10	Submission of relevant project details along with purchase order completion certificate clearly specifying type of business	Total value of such projects counted in lakhs of rupees: < 10 →0 marks Between 10 and 20 → 3 marks Between 20 and 30 → 5 marks Between 30 and 40 → 6 marks Between 40 and 50 → 7 marks Between 50 and 60 → 8 marks Between 60 and 100 → 9 marks > 100 →10 marks
5	Experience in Project Managem ent	5	Submission of details of employees having PMP certification or having post graduate degree with more than 10 years experience in IT	0 →0 marks 1 → 1 marks 2 → 2 marks 3 → 3 marks 4 → 4 marks 5 → 5 marks > 5 →5 marks

Table I(b) : Point System for Evaluation of Technical Proposal – Part B – Technical Solution

S. No	Criteria	Max. Marks	Response Expected	Evaluation Criteria
1	Understanding of System Requirement Provided in Annexure A	5	Able to provide a clear picture of System Requirement during technical presentation	No understanding – 0 marks Poor understanding– 1 marks. Fair understanding – 2 marks Good understanding – 3 marks Very good understanding – 4 marks Excellent understanding - 5 marks
2	Soundness of proposed solution	20	The viability and optimality of the technical solution proposed.	Non-viable – 0 marks For viable solutions, the marks will be based on optimality, as decided by technical committee, based on solution provided (including hardware, and software) in the proposal and technical presentation.
3	Implementation time	10	Time taken to implement the proposed solution, as indicated in the technical proposal submitted.	The timelines specified will be evaluated with reference to the feasibility of the strategy adopted, and modified if warranted. Among the viable solutions, the one with minimum timeline will be assigned full marks. One mark each for every two weeks will be reduced for others (with the constraint that there will be no negative marks).
4	Strategy for change management from current manual system to the new	10	The viability and optimality of the solution proposed for change management	Non-viable – 0 marks For viable solutions, the marks will be based on optimality, as decided by technical committee, based on solution provided and technical presentation .
5	Strategy for training and hand-holding	10	The viability and optimality of the solution proposed for change training and hand-holding	Non-viable – 0 marks For viable solutions, the marks will be based on optimality, as decided by technical committee, based on solution provided and technical presentation on it.
6	Strategy for upgradations, after sales support, and AMC	5	The viability and optimality of the solution proposed for these post first year of operation	Non-viable – 0 marks For viable solutions, the marks will be based on optimality, as decided by technical committee, based on solution provided and technical presentation on it.

Only bids having a minimum score as decided by the evaluation committee will be considered for financial evaluation.

7. Opening of Price bid and Selection of Winning bid

After the evaluation of Technical Bids, NIRT shall notify the bidders who's Technical Bid were considered acceptable, the date, time and place for opening of the Financial Bids. The notification may be sent by registered letter, fax, or email.

The Financial bid for the technically qualified vendors shall be opened in the presence of bidders who chose to attend.

The winning bid will be selected under the Quality-and Cost-Based Selection (QCBS) procedure described below:

Let F_1, F_2, … F_n be the financial figures quoted in the bids that are opened, and $\mathbf{F_{min}}$ is in **least** among them. The financial score of i^{th} bid will be calculated as $Sf_i = \mathbf{F_{min}} \times 100 / \mathbf{F_i}$.

Similarly, let T_1, T_2, ….T_n be the marks assigned by the technical evaluation committee for the various bids as per process set out in section 6, and $\mathbf{T_{max}}$ is in **highest** among them. The technical score of each bid will be calculated as $St_i = \mathbf{T_i} \times 100 / \mathbf{T_{max}}$.

The final score of the various bidders will be computed as $0.75 \times \mathbf{St_i} + 0.25 \times \mathbf{Sf_i}$. These will be computed and sorted in **descending** order. The winning bid will be the one with highest score.

8. Signing of the contract with the selected bidder

A letter of intent (LoI) will be issued to the selected bidder either on the day of opening of the price bid or the next working day. The contract between the bidder and NIRT (draft in Annexure E) will be signed within 15 days. The bidder will submit a performance bank guarantee and a bank guarantee for advance as given in as indicated in annexure III of this contract, at the earliest but in any case not later than 5 calendar days of signing of the contract. Failure in the above regards will make him ineligible, resulting in forfeiting of earnest money. The work maybe started immediately after the submission of the bank guarantees.

END OF SECTION I

SECTION II : INSTRUCTION TO BIDDERS (ITB)

1. The bid should be valid for minimum sixty days (60 days) from the date of opening the Price Bid. NIRT may ask bidders to extend the period of validity.
2. The **installation** shall be within **180 days** from the date of order. The operationalisation should be completed within **90 days** of installation.
3. **System specifications for the Hardware**: The bidder should ensure to quote only for reputed brand and make meeting national and international standards.
4. In case of any discrepancy between rates mentioned in figures and words, the latter shall prevail. If there is any discrepancy between the unit price and the total price, the unit price shall prevail and total price shall be corrected.
5. EMD is liable to be forfeited and bid is liable to be rejected, if the bidder withdraws or amends impairs or derogates from the tender in any respect within the validity period of the tender.
6. The EMD of all unsuccessful bidders will be returned as early as possible within the Bid Validity period but not before 30 days of the issue of the Work Order. No interest will be payable by NIRT on the EMD. The earnest money of successful bidder shall be returned after acceptance of the order and submission of security deposit.
7. Rates should be quoted towards Development, Supply, Installation and Commissioning and holding support for one year on turn- key basis of Bacteriology Laboratory Automation System accordingly by giving the basic price, VAT, Service Tax, etc. wherever applicable on the day of submission of the bid. The rate should be quoted in INR for the entire job to be done at site BOTH IN FIGURES AND WORDS. In case the bidder chooses to omit any tax, levy, etc., applicable at the time of quoting, it will be assumed that the same is absorbed in the price quoted.
8. Govt. levies like VAT, Service Tax, etc., shall be paid at actual rates as applicable from time to time.
9. NIRT reserves the right to accept / reject the offers or cancel the whole tender proceedings without assigning any reason whatsoever. Offers through Email / Fax, or open offers in any form shall not be accepted. Late / Delayed offers shall not be accepted under any circumstances. Incomplete offers are liable to be rejected. In case the specified date for the submission of offers being declared as a holiday for NIRT, the bid-closing deadline shall stand extended to the next working day up to the same time
10. Any attempt of negotiation on the part of the bidder (other than the negotiation permitted with the negotiation committee duly formed by NIRT), directly or indirectly, after submission of tender, with the authority to whom he has submitted the tender or authority who is competent to finally accept it, or any endeavor to secure any interest for an actual or prospective bidder or to influence by any means the acceptance of a particular tender will render the Bidder's tender liable to be rejected .
11. In order to clarify any points related with any of the clauses or scope of work/services to be executed under the contract, a PRE-BID MEETING is scheduled at 11:00 AM on 22/11/2013

at conference hall at NIRT. Any clarifications sought in this maybe submitted in writing to NIRT, preferably by e-mail, latest by 17:00 on 20/11/2013.

12. **Unsatisfactory Performance:** NIRT shall have the sole right to assess the performance of the tendered job during primary, intermediate and or final phases, and reject the same without assigning any reason/ explanation to the bidder, if the performance is found to be unsatisfactory as per norms of NIRT. The decision of NIRT will be final and binding on the supplier.
13. **Disclaimer:** This Tender / Request for Proposal(RFP) is not an offer by NIRT, but an invitation for bidder's response. No contractual obligation whatsoever shall arise from the tender Process.
14. **Price Basis: Turn-key-basis at NIRT, Mayor Sathiyamoorthy Road, Chetpet, Chennai.** Price quoted should be in the prescribed format as per **Annexure E**. No "Form C / D" shall be issued. The quoted price will be considered firm and no price escalation will be permitted till completion of works in all respects.
15. **Payment Terms:** The payment will be released in stages as per the reaching of the milestones indicated in Table below.

Sl.No.	Mile-Stone	% of Total Contract	Proof Documents for Release of Payment
1	Advance	25	Signing of the contract and submission of the bank guarantees for the advance and that for contract performance
2	Installation	25	Presentation of the Installation Certificate accepted by NIRT
3	Operationa-lisation	40	Presentation of the certificate from designated authority in NIRT stating that the operationalisation of the entire job is completed to the satisfaction of the users.
4	Completion of one year of Installation	10	Nil. Amount will be released within 12 months of reaching of milestone 2 or 9 months of milestone 3 whichever is later.

16. **Penalty for Delayed Services :**Penalty / Liquidated Damages shall be charged @ 0.5% of the contract value per week subject to maximum of 5% of actual order value (to be computed after completion of system installation), in case of delay beyond 6 (six) months from release of advance amount.
17. **Performance Bank Guarantee for Contract:** Valid for the entire contract including warranty period, is to be provided towards 10% of actual order value, from any scheduled bank.
18. **Warranty** : All the items covered in the Bill of Material (BOM), shall carry One Year Onsite Comprehensive Warranty with 4 hours response time (including Labour, maintenance, troubleshooting, installation of OS, replacing Faulty Spares, etc.). The service support / warranty services have to be provided at NIRT, Mayor Sathiyamoorthy Road, Chetpet, Chennai. The repairing / rectification, if any of the items under warranty must be done at site only. The bidder should submit along with the technical bid, the detailed plan for providing installation and warranty services

END OF SECTION II

Annexure-A

Scope of Work of System to be Implemented

1. Overview

Laboratory investigation is the prime means of diagnosis in modern medical practice. The process includes (a) registering of patient (b) sample collection (c) stages of investigation (d) result entry (e) result validation and (f) final reporting. The Laboratory Information System (LIS) provides a framework for the systematic completion of these activities. Among the many challenges that need to be surpassed for an effective implementation of a computerised LIS are over burdened laboratory personnel, space constraints in the laboratory and limited computer and network access.

The investigation system in the Bacteriology laboratory is characterised by predominantly manual operations using human eye (assisted by microscopes) after chemical procedures like smearing, culturing and incubation. Some of the procedures can be completed in a few hours, but others require many months. Due to this, the laboratory will have to maintain a large number of samples in many stages. The LIS system tracks all these to ensure that there is no mix-up in the sample creation, processing and reporting. This needs a fool proof strategy that precludes the chance of errors at each stage by a process of cross checking.

A current manual LIS for bacteriology laboratory involves maintenance of many forms, records, and registers where the testing technicians enter the results and verifiers verify them. The process is labour intensive and the resulting fatigue is affecting the turn-around time for obtaining the final results. Computerization of the LIS in the bacteriology Laboratory aims to solve these issues by automating the processes wherever possible.

NIRT routinely collects thousands of sputum samples from patients per month. These samples undergo various tests during their preservation that lasts six months to one year. The current process in NIRT is based on human readable manual labels indicating a distinct lab number for each sample. These are generated and pasted to various samples. These are visually inspected by expert technicians periodically for microbe detection during this long period of incubation. The results are initially recorded in note books, verified by a second technician for confirmation and reentered into registers. The entries from the registers are copied by the Statistics department. It connects the lab number with the patient identification number and makes the result available in the medical record of the patient. The consulting doctor becomes aware of the result only after this.

The current process of manual recording of test results to various records, forms, registers, etc. is tedious and prone to manual errors. The operations are spread over many locations. The inspection process requires space for keeping the samples and in many locations, space is a

premium. An automation system with traditional desktop computer with its large footprint is not viable in these locations.

Emergence of Netbook/Tablet PCs operating with wireless communication presents a new opportunity of automation. Such an automation system requires machine readable labeling system. Bar codes provide the ideal solution here. The current project proposes the business process re-engineering of the existing LIS to one using Wi-Fi enabled Netbook/Tablet PCs and bar codes. The system does not require any costly hardware. Use of Wi-Fi as the communication medium allows faster deployment.

This document presents the salient features of the system proposed to be developed under the project. It is organized as follows: Section 2 describes the current workflow in Bacteriology Laboratory in NIRT. Section 3 gives a reference design for the proposed automation system that uses a set of Tablet or Net PCs for the HMI interface and a separate Management Server for the business, logic and control functions. The HMI interface consists of a number of control tasks each implemented as separate user application that would automate one section of the current workflow.

The bidder is free to use the above reference design or can suggest a more optimum modified design. In either case the work has to be completed on turn-key basis and the responsibility of operationalisation of the system rests with the bidder. The pre-conditions if any, required from NIRT in this regard are to be clearly stated in the technical bid submitted.

2. Existing Workflow in Bacteriology Laboratory

The present workflow in the bacteriology laboratory consists of:

- Registration
- Lab Reception
- Smear Test
- Culture Test
- Drug Susceptibility and Confirmation Tests
- Identification and Subculture
- Combining of results at Statistics
- Advice by Medical Officer

These are described in the following subsections.

2.1 Registration

The registration is the first process seen by the patient. Fig 1 gives the workflow. It is done at the clinical reception and bacteriology lab is not involved in this. The process enters the demographic details of the patient into the registers and forms maintained by the system. From the reception, a bottle is provided to the patient to collect the sputum sample and the bottle

number is recorded. After completing the registration process a treatment ID card is given to the patient (Fig 2) for future reference. This ID is made available in the lab reception.

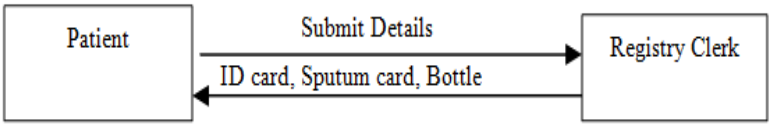


Figure 1: Registration Workflow

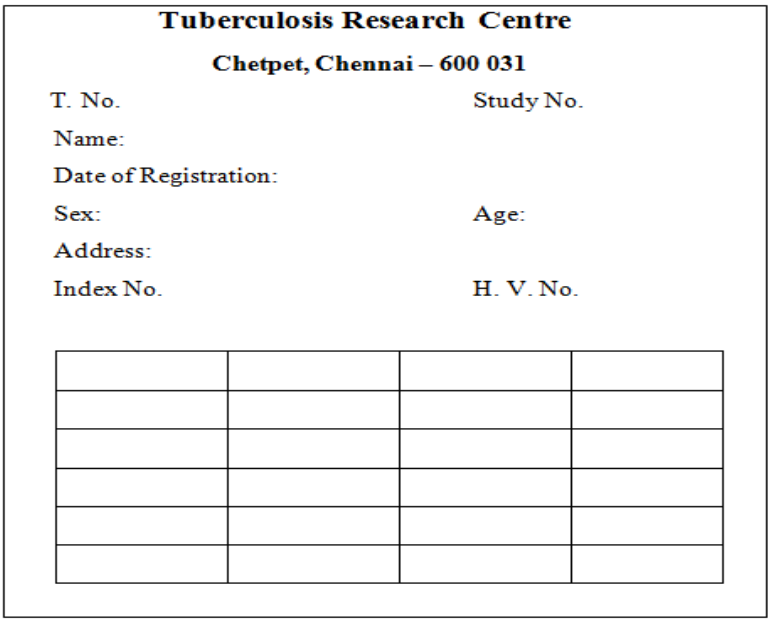


Figure 2: Format of Patient ID Card

Further details of this process are given in section 2.2.1.

2.2 Lab Reception

After the registration the patient submit his sputum specimen at the lab reception. The unique lab number for each specimen is assigned over here. The tightly packed specimen bottle is kept immersed in disinfectant solution for a specified period. An analyst processes samples in batches. A batch consists of 12 samples. Then, each batch is send to the Bacteriology laboratory. The details of this are further elaborated in the following subsections.

2.2.1 Specimen Reception & Numbering - General Process

A good sputum sample should consist of recently discharged material from the bronchial tree. Quality of the specimen implies the presence of mucoid or mucopurulent material. Ideally a sputum specimen should have a volume of approximately 5. 0 ml.

There are mainly two kinds of specimens received at lab reception. They are sputum specimen and extra pulmonary specimens such as urine, bronchial wash, ascetic uid CSF, pus, biopsy material, etc.

Sub centers such as Tambaram Sanatorium, GH and Vellore receive these specimens directly from patients or through health visitors or attendants. From Madurai and Thiruvallur sputum specimens are received in bulks through Lab messengers.

Referred patient's specimens may be directly referred to TRC from outside such as ITM and GHTM for Sputum AFB culture and sensitivity testing. Extra pulmonary specimens may be referred from other hospitals and clinics (Govt. & Private) for AFB culture and sensitivity. Sputum or Urine specimen received for opportunistic infection and direct cultures may be received for DST/ ID.

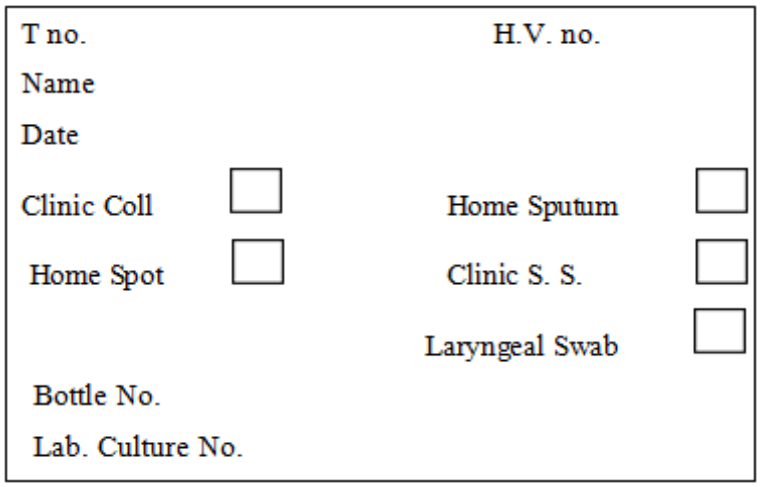


Figure 3: Format of Sputum Card

2.2.2 Specimen Reception and Numbering - Workflow

There are mainly five kinds of specimen reception – those from TRC patients, those from Tiruvallur and Madurai, from sub centers of TRC, from referred patients, and specimen received in a packed container (by courier). These are described below.

2.2.2.1 Specimen received from TRC patients

TRC registered patients bring sputum specimen and sputum card to the lab reception. There the concerned staff checks if the bottle is tightly closed; if not, he instructs the patient to close it tightly. Then he verifies the bottle number on the bottle cap and the sputum card. If the sputum volume is less than 5ml he instructs the patient to collect more samples.

The sample is then placed in a rack that can hold 12 such bottles, kept in the 5% phenol tank in such a way that the bottles and caps are completely immersed. The bottles are left like this for at least 30 minutes.

The patient is given an acknowledgement chit meant for the registration clerk to indicate that he had submitted the sample. A unique lab number is assigned to each sample and same is entered on the corresponding sputum card.

Sl no.	Date of specimen reception	Type	Bottle no.	Name	T no.	Lab no.

Time:

Figure 4: Format of Sputum Form

The concerned staff now enters the details to the Bacteriology Sputum Form. The details entered include Date of specimen reception, Type of specimen, Bottle no., Name of patient, T no. and Lab no. Fig 4 shows the format of Bacteriology Sputum Form. This form has a carbon copy. Original copy is send to the Statistics department and the carbon copy is kept in the lab reception itself.

After receiving 12 samples, the set of bottles are removed from the tank using tongs and rinsed in running water. The time of receipt of the 12th specimen is entered on the corresponding Bacteriology Sputum Form. The volume and consistency of each sample is noted in the duplicate copy of the Bacteriology Sputum Form kept in the reception. The completed set (12 samples) is sent to the lab through bacteriology lab attendant along with the sputum cards and Bacteriology Sputum Forms.

A very similar process is adopted for sputum samples received for opportunistic infections and in this case the batch is send to the Opportunistic Infection Laboratory. Similar process is adopted for urine specimen reception for biochemical investigations and in this case they are sent to the biochemistry department along with the urine cards through their staff.

2.2.2.2 Specimen received from Tiruvallur and Madurai

In this case, the patients are not physically present and the specimen along with documentation arrives in batches. The actions consist of:

- Decontaminate Specimen with 5% of Lysol tank for 30 minutes in wash up room.
- Check the bottle number with request form.
- Assign lab number to the bottle and document it in separate note.
- Send specimen to bacteriology laboratory.

2.2.2.3 Specimen received from Sub centres of TRC

Specimens are received through Health visitors along with Sputum Specimen Form (Fig 5)mentioning the Name of patient, Registration no., Date of specimen reception, Type of specimen and Bottle no. This form has two more carbon copies. These copies are given to the Statistics department.

Sl no.	Date of specimen reception	Type	Bottle no.	Name	T no.	Lab no.	Result

Time:

Figure 5: Format of Sputum Specimen Form

- The activities on reception on these specimens are as follows:
- Check the number on the form and the bottle cap.
- Decontaminate as described early.
- Assign lab numbers for specimens and enter in Sputum Specimen Forms.
- Send the samples to the Bacteriology lab through an attendant along with corresponding Sputum Specimen Form.
- When extra pulmonary specimens are received from TRC or sub centers: Assign SP prefix in the lab number.

Note that the lab numbers kept for each sub-centre has a different prefix (Fig 6) allowing one to track these samples sub-centre wise.

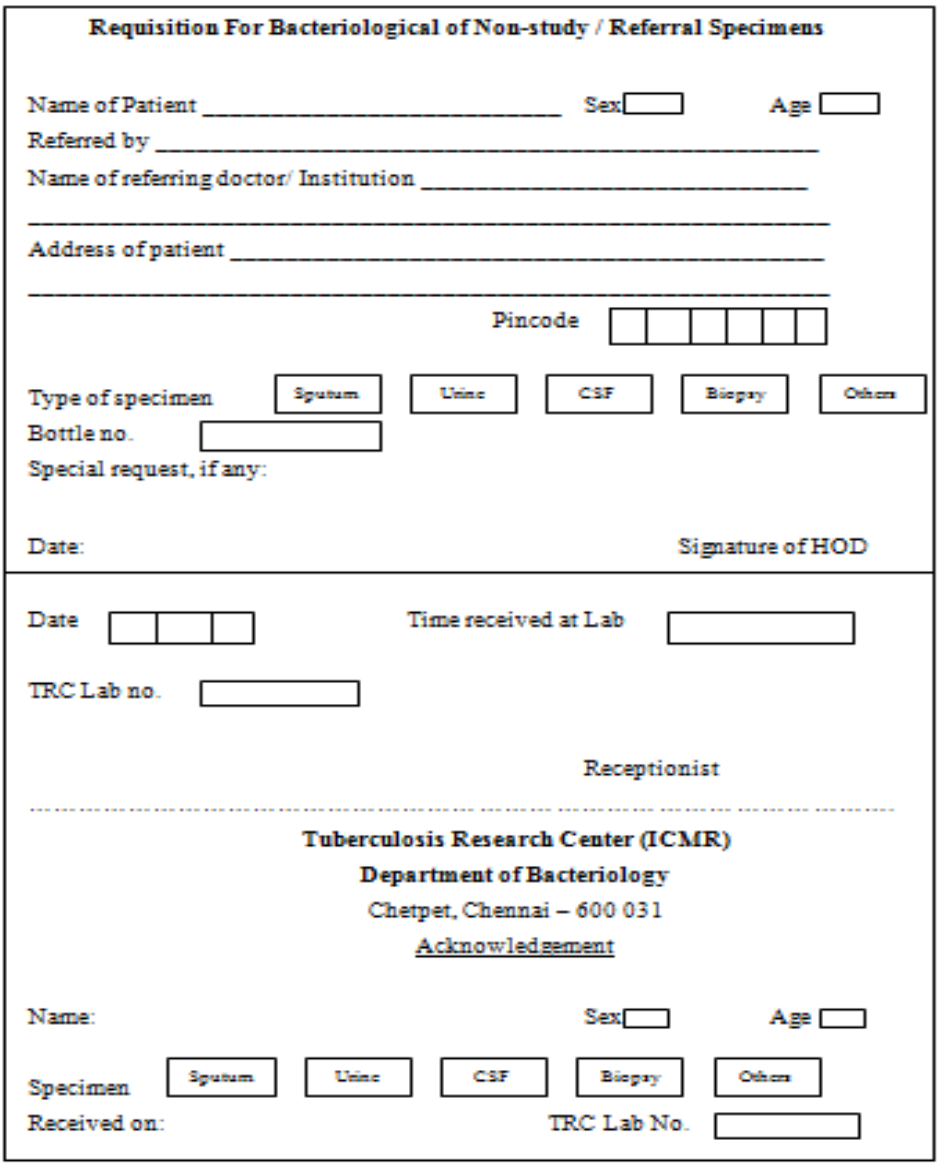
Study center	T. No.	Prefix lab no
San (Tambaram)	HT	B
GH	HG	S
VELLORE	VO	E
MDR STUDY		DP
MAURAI	M	D
TOBACCO SURVEY STUDY		TS
CHENNAI DISEASE SURVEY		CS
REFERRAL and GHTM OP CASES		RF
STUDY PATIENTS -EXTRA PULMONARY		SP
REFERRAL CASES (EXTRA PULMONARY)		RFEP

Figure 6: Lab Numbers Allotted to Sub Centers

2.2.2.4 Specimen received from referred patients

Many patients arrive at NIRT with requisition slips or letters for diagnostic services. The workflow in the lab reception in these cases is as flows:

- Check the requisition or Referral slip or letter from the patients.
- If sputum for AFB and Culture & Sensitivity is requested, issue a numbered sterile McCartney bottle wrapped with tissue paper to the patient. Mark the bottle number on the referral slip itself.
- Instruct the patients to collect 5.0ml of the sputum in the bottle. (Approximately mark the level using marker).
- Document the Patients name, Age, Sex, Sputum collection date, Referral doctor or institute and Patients / Clinicians address in the Sputum Referral form. Fig 7 shows the format of Sputum Referral Form.
- After receiving the sputum specimen, note the consistency and volume of the specimen and immerse it in 5% phenol.
- Assign the lab number in the form and issue the perforated Acknowledgement Slip to the patient which has Patients name, Age, Sex, Date of specimen and Lab number.
- If the specimen is the extra pulmonary, enter the Type of specimen, Date of collection.
- Allot RFEP lab number and send to the lab immediately.
- For sputum and extra pulmonary specimen, instruct the patient to bring this slip after three months for the report.



Requisition For Bacteriological of Non-study / Referral Specimens

Name of Patient _____ Sex☐ Age ☐

Referred by _____

Name of referring doctor/ Institution _____

_____

Address of patient _____

_____

Pincode ☐☐☐☐☐☐

Type of specimen Sputum Urine CSF Biopsy Others

Bottle no. ☐

Special request, if any:

Date: Signature of HOD

Date ☐☐☐ Time received at Lab ☐

TRC Lab no. ☐

Receptionist

Tuberculosis Research Center (ICMR)

Department of Bacteriology

Chetpet, Chennai – 600 031

Acknowledgement

Name: Sex☐ Age ☐

Specimen Sputum Urine CSF Biopsy Others

Received on: TRC Lab No. ☐

Figure 7: Format of Sputum Referral Form

The patient or an attendant can come with a request for collection of extra pulmonary specimen (biopsy, tissue). The workflow in this case is as follows:

- Issue a Kirchners liquid medium bottle / a numbered sterile bottle (pus, CSF, gastric lavage etc.).
- Instruct the patient attendant to bring the sample on the same day of collection.
- Issue 3 sterile wide mouthed bottles for collection of urine samples.

- Instruct the patient to collect early morning and mid stream urine and to bring it as early as possible.

2.2.2.5 Specimen received in a packed container by courier

The specimen may be sent from distant locations in packed containers delivered by various courier services. The workflow in this case is as follows:

- Receive all the packed containers from the couriers or individuals and send to the laboratory. Open the parcel in the bio safety cabinet and note the nature of the specimen.
- If the specimen is sputum, send the same to the lab reception along with the request form / letter, for decontamination or decontaminate in the lab in bread boxes.
- Allot the corresponding RF number on the RF form and send to the lab along with specimens. If the specimen is direct culture, send the request form to the Lab reception for allotting the referral lab number.
- Whenever there is a special request for BACTEC (RF, SP specimen study 25) write Bactec on the bottle cap or on the side of the bottle and the request form document in separate note.

2.2.2.6 Work Procedure at Lab Reception at End of Day

Lab reception maintains a diary in which the technician enters the first and the last number against each of the studies. Samples received on holidays should be stored as follows:

- CPC samples - at room temperature;
- Sputum and other biological specimens - in the cold room.

2.2.3 Specimen Reception and Numbering – Logistics

Specimen reception and numbering is handled by a technical staff in the lab reception. A lab attendant sends the received specimens to the Bacteriology lab. The specimens are received from Monday to Friday between 7AM and 2.30PM. Approximately 35 to 40 specimens are received per day.

After the registration the patient submit his sputum specimen at the lab reception. The unique lab number for each specimen is assigned over here. The tightly packed specimen bottle is kept immersed in disinfectant solution for a specified period. An analyst processes samples in batches. A batch consists of 12 samples. Then, each batch is send to the Bacteriology laboratory.

2.3 Smearing and Culturing

On receiving a rack of 12 specimens along with the corresponding sputum cards and specimen form, the technician in the Bacteriology lab verifies the bottle number and lab number and then arranges the bottles in the lab number order. Then they prepare smear and cultures for each sample. The details are given in following sub-sections.

2.1 Smearing and Culturing – General Process

In smearing only one slide is prepared. The slide has same lab number as the bottle had. For the smear, Auramine Phenol Staining is used. With Auramine staining, the bacilli appear as slender golden yellow fluorescent rods, standing out clearly against a dark background. A counter-stain is employed to highlight the stained organisms for easier recognition.

In culturing two slopes of cultures are prepared. Both the slopes use Lowestein - Jensen (LJ) medium as the culture medium. The two slopes have same lab number as the sputum sample had.

2.2 Smearing and Culturing – Work Flow

Fig 8 gives an overview of the smear and culture workflow. Note that both operate on the sputum sample sent.

The workflow for smearing is as follows:. Select the thick viscous portion of the sputum. With the help of a loop spread it evenly on the glass slide, and air dry and heat fix them.Place the slides on a staining rack, with the smeared side facing up; the slides do not touch each other. Flood the slides with freshly filtered 0.3% Auramine-phenol. Let them stand for 7-10 minutes. Then wash well with running tap water, taking care to control the flow of water so as to prevent washing away of the smear. Drain the water from the slides. Then decolorize by covering completely with 1% acid-alcohol for 1-2 minutes. Wash well with running tap water. Drain the water from the slides. Counter stain with 0.1% potassium permanganate for 30 - 45 seconds. Wash well with tap water and allow the slides in slanting position to dry in hot plate maintained at 75 - 80o C. Then bring the smear slides to the smear reading room.

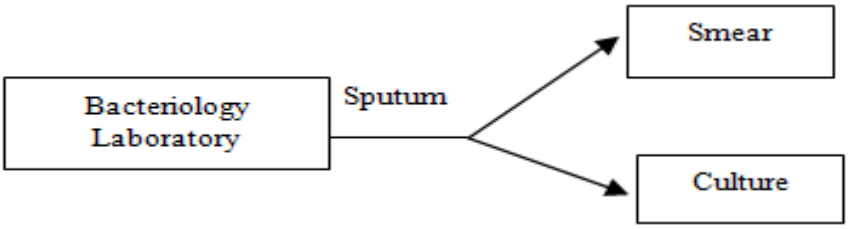


Figure 8: Overview of Smear and Culture Workflow

After preparing the smears the technician make an entry on a diary (Fig 9), giving the date and time of smear preparation, Lab no. (From - To), Batch no. and the name of the technician.

Date:		
Time:		
Batch no.		
Lab no. (from - to)	Smear / Culture	Technician's name

Figure 9: Smear and Culture Diary Format

The workflow for culturing is as follows:. First process the sputum samples that is decontaminated to liquefy the specimen. For this Modified petroffs method is used. Decant supernatant, prepare the deposit smear and inoculate the deposit on to two slopes of LJ medium. Incubate all the LJ media slopes at 37C for a minimum of 10 days and maximum of 8 weeks. After the culture preparation the technician makes an entry on the above diary and then the initial bottle is discarded.

2.3 Smearing and Culturing – Logistics

Smearing and culturing is done by technicians and technical assistants in the Bacteriology lab. Maximum of two technicians prepare the smear and culture at a time. They prepare it within a safety cabinet. On receiving a rack of 12 specimens they start the preparation. Smearing and culturing is done from Monday to Friday between 8AM and 4.30PM. Approximately 100 to 150 smears are created per day. For each sample a smear and duplicate culture is done on LJ medium.

2.4 Smear Reading

On receiving a batch of smeared slides and the corresponding entry in the smear preparation diary the technician in the reading room inspects the slides to determine the presence of Mycobacterium tuberculosis. This activity is called smear reading.

2.4.1 Smearing Reading – General Process

Smear reading is done by two technicians first by the reader and second by the checker. They use a smear reading note book. Before starting the reading they enter the lab numbers of slides which they are going to read, based upon the smear preparation diary on the reading note book. After reading each slide, they grade them as either positive or negative.

2.4.2 Smearing Reading – Workflow and Logistics

In smear reading the reader reads each slide using an iLED microscope and marks the result to the corresponding lab number on the smear reading note book. Report positive if a smear contains a minimum of 4 AFB of typical bacilli in at least 100 fields. If less than 4 bacilli are

present, report as negative. However, the number of bacilli is noted in the smear record book. He, then grade the positive smears into three degrees of positivity using the high power field (HPF) as given in fig 10.

After this the checker checks all positive smears and randomly selected 50% negative ones and he makes a tick mark for the same result as readers on the book. If the checker finds any change he makes an amendment. Fig 11 shows the format of Smear reading notebook. After this the smear results are given to the Statistics department and from there it is given to the medical officer. Lab number and the smear result goes to the statistics department.

In statistics department the smear result of the specimens from sub centers are entered in the corresponding Sputum specimen form and send to the sub center.

No. of bacilli	Grade
At least 4 in 100 HPF or <6 per HPF in at least 50 HPF	1+
6-100 in at least 50 HPF	2+
> 100 in at least 50 HPF	3+
No bacilli or (0-3) 100 HPF	Negative

Figure 10: Scheme for Smear Grading

Date:		
Time:		
Lab no.	Reader's entry	Checker's entry
Name of reader:		
Name of checker:		

Figure 11: Format of Smear Reading Note Book

Smear reading is generally done by two technicians using iLED microscope. This is attempted during the normal timeslot of 10:00 AM to 4:30 PM on working days. The results are reported to the Statistics department.

2.5 Culture Reading

In culture reading section cultures are examined to know the growth of Mycobacterium tuberculosis. This activity is called culture reading. The process is described in the following sub-sections.

2.5.1 Culture Reading – General Process

Four readers perform the culture reading process. Mondays are designated as culture reading days. It is performed between 8.30AM and 12.30PM. Approximately 5000 cultures are read per week. Subsequent to this, culture selection is done by HOD. It is done on same day afternoon.

In culture reading, cultures are examined starting from 8th week cultures to 1st week. (1st wk is decided after completing 10 days up to previous Friday of inoculation). Typical colonies of Mycobacterium tuberculosis are rough, buff, tough, non-pigmented (cream colored) and slow-growers, i.e., Colonies appearing after one to two weeks after inoculation. The growth of culture is recorded in the Smear & culture volume which is given from statistics department.

2.5.2 Culture Reading – Workflow

In culture reading the technicians read two slopes of each sample and grades the growth of it. There may either be positive or negative. The positive slopes are graded as indicated in Fig 12.

While taking the reading, typical cultures, doubtful cultures (atypical morphology), and contaminated cultures are kept separately in a rack for further confirmation (Selection of cultures). The result of culture reading is entered in the Culture volume. The entries in the culture volume are Date of specimen, Type, Name of patient, DST volume page, Study no., DST request, T no., Smear result, Lab no., Culture results, Date of recording final result, Amendment. Fig 13 shows the format of Culture volume.

No. of colonies	Grade
<19 colonies	Write actual number of colonies
20-100 discrete colonies	1+
> 100 colonies	2+
Confluent growth	3+
Contaminated	* / * ID

Figure 12: Scheme for Culture Grading

Date of SP	Type	Name	DST vol. page, Date	Study no.	DST request	T no.	Sm	Lab no.	Culture results (weeks)									Date of Rec.	Amend.
									1	2	3	4	5	6	7	8	Final		

Figure 13: Format of Culture Volume

If both slopes are positive in the same week, the highest degree of Growth is recorded in the final result column. If one slope is positive and the other slope is negative, the culture is reported as positive in the final result column and in this case reading of the second slope is continued until 8th week. If it becomes positive, it is kept as duplicate.

Non Negative culture form : On every Monday, a Non Negative culture report is generated and sent to the statistics. (Fig 18)

If one slope shows UMB and the other is Negative, the final result is entered as Neg/UMB with grading at 8th week. If both slopes are UMB on different weeks, the growth of first slope is entered as the final result. If one slope is contaminated the final result depends on the second slope as indicated in Fig 14.

The head of department (HOD) of Bacteriology checks all contaminated cultures, UMB and Positive slopes. Doubtful cultures are re-confirmed by Ziehl-Neelsen (ZN) staining for AFB.

Selection : Selection is a process of decision making on all the non negative cultures

On completion of culture reading, HOD uses the patients laboratory culture cards (Fig 15) for all positive cultures to decide the course of DST for a particular sample. (HIV patients are demarcated by differently colored culture card). He enters the laboratory number under the appropriate month of treatment, and indicates the sensitivity tests to be set up in the appropriate column in the culture register.

In Fig 15, the pretreatment samples numbers are written by hand as items 1 to 4 in the pre-treatment column. Study number is included as an additional column. 1-40 indicated in this record stand for the month after start of treatment and in each cell, the corresponding lab number is written by hand. The record gives a consolidated document corresponding to the patient.

First slope	Second slope	Final reading
*	Neg	Neg
*	*	Cont
*	*ID UMB	UMB
Neg	*ID UMB	UMB
+	Neg	+
+	++ (different weeks)	+
+	++ (same week)	++
*ID UMB	+	+
*	+	+

***UMB should be mentioned with grading**

First Slope	2nd slope	Final result
+*	+ (at different week)	+ *
+	+ (Same week)	+*
+*	++(Same week)	++
4 col	6 col (Same week)	10 col
8 col	10 col * (same week)	8 col
*ID UMB	+ (at Same or different week)	+
*ID UMB	+ (at Same or different week)	+
*	+ (at Same or different week)	+

Figure 14: Culture Result Finalisation Table

For pre treatment cultures, two (different lab numbers) positive cultures for sensitivity tests are selected and a third positive culture is stored in deep-freeze (-80 C). In case of change of treatment, two cultures during the month of change is selected and both are set up for DST (to the old drugs as well as the new drugs). This is done by placing a tick on the lab card against the culture selected for DST and on requests in the appropriate column of the culture register for the selected cultures. After this, the requests for DST on the remaining cultures for that month

in the culture register are crossed out. After the completion of treatment ie Appox after 6 months if the patient is positive another culture is stored in deep-freeze (-80 C) for RFLP.

Laboratory Culture Number Card			Regimen			
Name:			T no.	Sex:		Age:
Date Treatment Started:					Serial no.	
Pre-treatment:	1	2	3	4	5	6
	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31	32	33
34	35	36	37	38	39	40

Figure 15: Format of Laboratory Culture Card

Slopes for Subculture for storage and for ID test were also selected by HOD and relevant entries were made.

Sub-culturing workflow is as follows:

- Give Positive cultures not selected for DST and duplicate slope of the positive for sub culture.
- In case of two slope positive on the same week, one is given for the storage. Give duplicate slopes (if it becomes positive in subsequent week) for subculture.
- Enter the selected positive cultures separately according to study wise in the subculture note book.

A number of note book entries are performed in the culture reading section. They are used as follows:

- Enter starting and last number of cultures completing 8th week in a appropriate note book. These slopes are to be rechecked by a senior person before discarding.
- Cultures contaminated within 48hrs should be entered into the 1 st week note book (See fig 16) on completion of this period.
- If both slopes are contaminated, verify the sputum card and inform the clinician, if necessary.

Date:	
Lab No.	Result

Figure 16: Format of 48 hour notebook

Date:	
Lab No.	T no.

Figure 17: Format of flowchart book

The technicians maintain a Flow chart book (Fig 17) which contains the lab number and treatment number of all culture positive samples. They stripe the entry after entering it into the laboratory culture card. They also make a cross mark to the not admitted patients.

After completing culture reading in a week the technician make a list of non-negative culture results (Fig 18). This sheet contains the lab numbers of all cultures who got culture results as other than negative. He also records the 8th week starting number, last number and 1st week last number.

Lab No.	S	H	R	E	K	Th	Of	-80° C		
								Lab No.	Study No.	T No.

Figure 29: Format of selected Culture Note Book

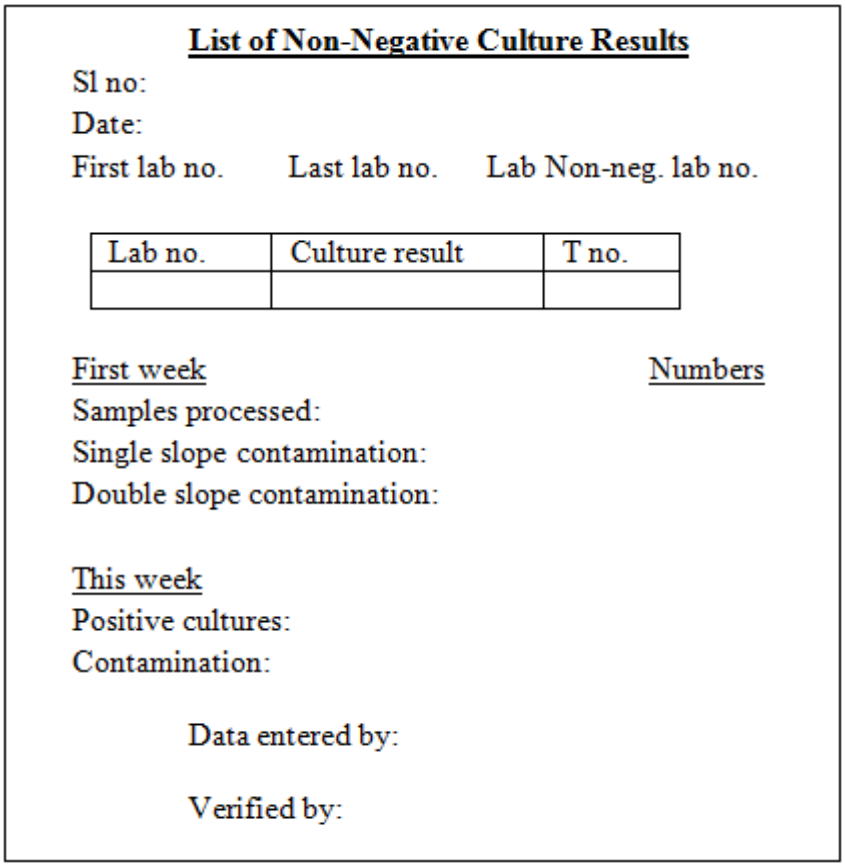
2.6 Sub-Culture

Selected slopes are subjected to subculture to confirm whether the growth is typical or atypical. At the time of culture reading, the examiner separates all positive samples to a rack. For subculture, all positive samples from different studies are collected and for only non-admitted patients. Currently two technicians are handling this procedure. Almost all the results of subculture are positive.

2.6.1 Sub-Culture – General Process

Every Monday when culture reading is completed sub culture slopes will be selected by the head of the department. If sufficient growth is not seen in culture slopes, spread the colonies in a loop and kept it for further incubation (1-2 weeks). In subculture, one L-J slope and one PNB slope are prepared. These two slopes have the same Lab number as the Sputum Card had. These two slopes then go to incubator for 28 days.

Currently Subculture is performed in culture reading room. Subculture set up can be done on any day. The reading is on Wednesday.



List of Non-Negative Culture Results

Sl no:

Date:

First lab no. Last lab no. Lab Non-neg. lab no.

Lab no.	Culture result	T no.

First week Numbers

Samples processed:

Single slope contamination:

Double slope contamination:

This week

Positive cultures:

Contamination:

Data entered by:

Verified by:

Figure 18: Format of non-negative culture sheet

2.6.2 Sub-Culture – Workflow

Fig 19 gives the sub-culture workflow. It consists of the following steps:

- Arrange the selected culture slopes in rack according to studies in ascending order. Then mark the Lab number and Serial number on the Bijou bottle.
- Arrange one LJ Slope and one PNB in a rack. Mark the Lab number and Serial number on the LJ Slopes according to the study.
- For the Preparation of Bacterial Suspension marked Bijou bottles are used. After 10 minutes the suspension from Bijou bottles are moved to one L-J slope and to one PNB slope. These two slopes are in separate bottles with the same Lab number. These two slopes kept in incubator for 28 days.
- The original culture slopes also will be kept in incubator for repeated test if needed.
- After 28 days, readings will be carried out by the technicians. The results are recorded in a daily diary and a sub culture register (Fig 20).

- The plain L-J slopes are then sent for the Niacin test. Based on these three results the final result is recorded.

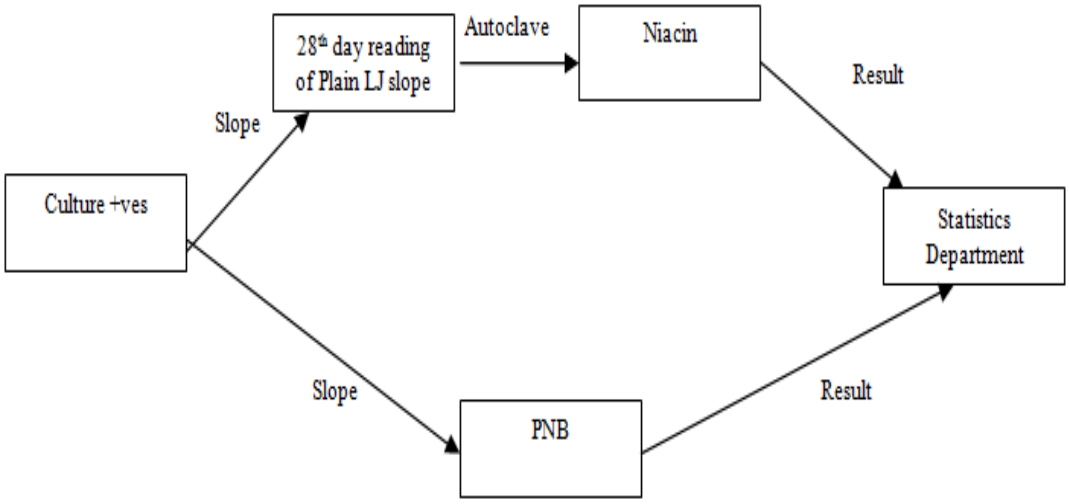


Figure 19: Sub-culture Workflow

Sno	Lab Number	28th day	PNB	Niacin	Remarks

Figure 20: Sub-culture Register

2.7 Identification (ID)

Following the culture reading, HOD will select and separate positives, query positive and contaminated cultures. Query positives and contaminated samples are to be further tested for growth for identification. The main aim of identification is to check whether the bacterium is AFB (Acid Fast Bacilli) or Non-AFB.

2.7.1 Identification – General Process

Identification consists of ZN (Ziehl Neelsen) smear and ID setup (Niacin, PNB and Catalase). Tuesdays are designated for ZN smear reading and ID culture reading is on Wednesday. Setup

can be done on any day based on the arrival of samples. If the ZN smear result is positive for AFB, we incubate the culture slopes for ID setup. For ID set up, PNB and Niacin tests should be performed. For that we make two LJ and one PNB slopes and incubate it at 37^{o}C for 28 days. After 28 days, we select one of the slopes from each culture and ensure that it contains more than 2+ growth with water of condensation for performing Niacin test.

Currently, Two technicians are engaged for doing identification. ID smear examination is on Tuesday 9.00 am to 2.00 pm. ID culture reading on Wednesday. Niacin test is done on Thursday before 12.00 pm.

2.7.2 Identification – Workflow

Fig 21 gives the ID workflow. It consists of the following steps:

- Arrange the culture slopes study wise in ascending order. Write the serial number on the lid of the culture slopes.
- Write the serial number, lab number and colony morphology in the ID note book. Color, appearance and grading of culture are recorded for describing colony morphology.

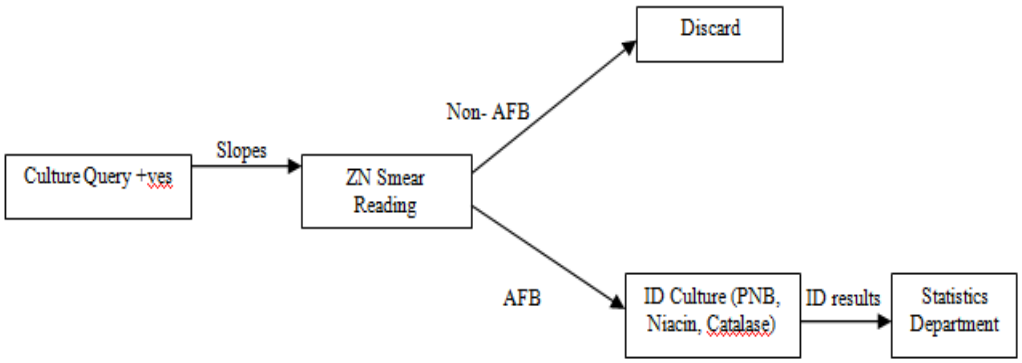


Figure 21: ID Workflow

- For ZN smear, write 3 serial numbers on single slide. ZN smear results are recorded on the ID note book and the results may be AFB or Non-AFB.
- If AFB, describe the bacterial morphology and incubate the culture slopes for ID setup.

- If Non-AFB, report as negative and discard the culture slope and document it as negative in the culture register. Enter the date of set up against the lab numbers in ID smear note book.
- The smear results for ID will be entered in non negative register as UMB/ Conta and will be sent to Statistical department most probably on the same day.
- Niacin, PNB and Catalase tests should be performed for ID setup. For that, select sufficient growth containing culture slopes and arrange the slopes study wise in ascending order. Enter the lab number and serial number (1, 2, 3,4, 5, etc) in the daily diary and ID register. To perform ID culture 3 slopes (Two LJ and one PNB) are needed. These 3 slopes are prepared by taking one portion of culture suspension from bijou bottle and inoculate it into two LJ and one PNB slopes. So write the lab number (last 3 digits only) and serial number using different color marker in bijou bottle cap. Then write lab number on two LJ and one PNB slope. Enter the details subsequently in ID culture note book leaving columns for 28th day reading on 2 LJ and 1 PNB slopes. Allot separate columns for entering Niacin, PNB, HPLC, TNP (Test Not Possible) and RPT (Repeat) results.
- After 28 days read the slopes and grade the growth.
- For Niacin test, select one of the slopes from each culture and ensure that it contains more than 2+ growth with water of condensation. Give Serial number for the slopes that are selected for Niacin test and enter in the Niacin notebook along with the Lab number. Give the culture slopes for autoclaving. Catalase test is performed only for CS studies.
- Final Results : Report the culture as typical, if no growth is seen in PNB and the Niacin test is positive. Report the culture as UMB in the ID culture note if there is growth on PNB and the test is negative for Niacin.
- If required for the cultures reported as UMB, the slope can be sent for further ID.
- If LJ or PNB are contaminated repeat the test.
- Report as Test not possible (TNP) if contaminated on repeated testing.
- If no growth seen in either slope repeat ID.
- Amend the report accordingly in the ID culture note book, culture register (volume) and the amendment note book.

Fig 22 shows the entries in the ID smear note book. The column for colony morphology is entered at the time of culture reading and the final column is filled after ZN smears reading. The culture setup date is also mentioned in the ID smear note book. Patient name is not present in the ID smear note book for CS studies. ID culture note book has the following entries and some space is allotter for writing Test Not Possible (TNP) and Repeat (RPT).

S. No.	Lab No.	T. No.	Patient Name	Colony Morphology	ZN Smear Morphology

Figure 22: ID Smear Notebook Entries

Fig 23 shows the format of ID culture note book. The Niacin register contains the lab numbers from DST, subculture and identification. Fig 24 shows the ID amendment note book. Fist five columns are filled during the culture reading and the last two columns will be filled after 28 days i.e. after performing PNB and Niacin.

Lab No.	T. No.	Patient Name	Colony Morphology	Smear Morphology	28	PNB	Niacin	HPLC

Figure 23: ID Culture Notebook Entries

Date	Lab No:	T. No:	Name	From	To	Sign

Figure 24: ID Amendment Notebook Entries

2.8 Drug Susceptibility Tests (DST)

Drug susceptibility tests should be performed in the following instances:

- For all pretreatment cases admitted in the study
- For relapse or re-treatment cases.
- To change the drug regimen when drug resistance is suspected.
- Undertaking drug resistance surveillance studies in a region/country.

2.8.1 DST – General Process

There are three methods used for determining drug susceptibility of Mycobacterium tuberculosis. They are:.

Absolute concentration method /Minimal Inhibitory concentration method (MIC method): This method uses a standardized inoculum grown on drug-free media and media containing graded concentrations of the drugs to be tested. Resistance is expressed in terms of the lowest concentration of the drug that inhibits growth (20 colonies) i. e., minimal inhibitory concentration (MIC). This method is greatly affected by inoculum size and the viability of the organisms.

Resistance ratio method: It compares the resistance of unknown strains of tubercle bacilli with that of a standard laboratory strain. Parallel sets of media, containing two fold dilutions of the drug, are inoculated with a standard inoculum prepared from both the unknown and standard strains of tuberclebacilli. Resistance is expressed as the ratio of the minimal inhibitory concentration (MIC) of the test strain divided by the MIC for the standard strain in the same set.

Proportion method: Proportion method is not commonly used in the routine NIRT study. It is used in RNTCP.

Maximum 4 technicians are responsible for performing DST. DST can be done on any day, weekly twice. Each technician takes approximately 3 hours to complete two trays. Each tray contains 10 samples. The date of preparation, drug, and batch no. is mentioned on the tray itself. All the works are carried out in the bio-safety cabinets.

2.8.2 DST – Workflow

From the selection process the culture desinnated for DST are collected. Drugs for each sample will be available on the repeat register and selected note book

In DST the technicians are arrange two plain slopes and single slopes for each concentration of the drug and a PNB slope. The procedure for the setting up of DST in different methods is described below.

The procedure for the setting up of DST in different methods is described below.

Absolute Concentration method /Minimal Inhibitory Concentration method (MIC method) : Fig 25 gives the drug containing media used for the absolute concentration method.

Inoculum preparation is as follows. With 3mm internal diameter loop (24 SWG nichrome wire) take 2/3 loop full of a representative sample (approximately 4 mg of moist weight) from the primary culture and place on the side wall of a bijou bottle containing 0.3ml double sterile distilled water. Vortex the bottle for 20–30 seconds and then add 0.7ml of double sterile distilled water. Wait for ten minutes. With 3mm external diameter loop (27 SWG nichrome wire) inoculate the all media containing the graded concentration of first and second line drug from lower to higher concentration.

Drug	Concentration of Drug (µg/ml)		
	$H_{37}RV$ (control strain)	Test strain	Test strain of Referred (RF)cultures
First line			
Streptomycin	2,4,8,16,32,64	8,16,32,64	16
Isoniazid	0.025, 0.05, 0.1, 0.2, 1, 5	0.2, 1, 5	0.2
Rifampicin	4,8,16,32,64,128	32,64,128	64
Ethambutol	0.5,1,2,4,8	2,4,8	4
Second line			

Ofloxacin	0.5,1,2,4,8	2,4,8	2,4
Kanamycin	2,4,8,16,32,64	8,16,32,64	32
Ethionamide	20,28.5,40,57,80, 114	20,28.5,40,57,80,114	80

PNB -500 µg/ml

Figure 25: Drug Containing Media in MIC

First line DST: 12 slopes to be inoculated (Isoniazid-3, Rifmapicin-3, Ethambutol-3, plain LJ-2 and PNB-1).

Second line DST: 16 slopes to be inoculated (Ofloxacillin-3, Kanamycin-4, Ethionamide-6, plain LJ-2 and PNB-1).

Resistance Ratio method: Fig 26 gives the drug containing media used for the resistance ratio method.

Inoculum preparation: It is same as Absolute concentration method (MIC). Inoculate slopes for control and test strains as shown in the above table. Inoculate only LJ 16 µg/ml for RF samples.

Bacterial Suspension: Prepare a suspension by scrapping approximately 4 mg moist weight of a representative sample (visualized as 2/3 loopful of 3mm internal diameter 24 SWG (Thick) wire loop) into 0.3 ml of sterile distilled water in a Bijou bottle. Vortex for 30 seconds to produce a uniform suspension and then add 7 ml of sterile distilled water to the suspension to make it approximately 1mg/ml (S). Keep this suspension on the bench for 15-20 minutes to allow the coarser particles to settle down. From this suspension make a 10-fold dilution by carefully adding 0.2ml to 1.8ml sterile distilled water (S1, 10-1). Prepare two further serial dilutions 10-2(S2) and 10-3(S3) are prepared in a similar manner. Inoculate one loopful (3 mm external diameter, 27 SWG Thin) on drug free and drug containing LJ slopes for S1 & S2 as shown in Fig 27.

Dilution	Plain		Drug				
			S	H	R	E	PNB
S	X						X
S1	X	X	X	X	X	X	
S2	X	X	X	X	X	X	
S3	X	X					
S4	X	X					

Figure 27: Drug Free and Drug Containing Slopes

Concentrations used

First line Drug

Dihydrostreptomycin : 4 µg/ml

Isoniazid : 0. 2 µg/ml

Rifampicin : 40 µg/ml

Ethambutol : 2 µg/ml

Second line Drug

Kanamycin : 30 µg/ml

Ethionamide : 40, &57 µg/ml

Ofloxacin : 2 µg/ml

Amikacin : 40 µg/ml

Capriomycin : 40 µg/ml

After preparing the drug containing slopes, they are stored up to 1 month in 4° C. After setting up of DST, enter the list of lab numbers setup on that particular date in the corresponding diary along with the technician's name. Mention the corresponding batch numbers of the drugs used. Fig 28 shows the format of diary. Later score the lab numbers for which the DST is setup in the selected culture note book along with the date. Fig 29 shows the format of selected culture note book.

Batch No. Date:	
$H_{37}RV$	
Lab No.	Drug
Technitian's Name:	Signature:

Figure 28: Format of DST Diary Entry

2.8.3 Drug Susceptibility Reading

DST reading is performed after 28 days of incubation. Wednesday 9AM to 12.30PM is designated as DST reading day. Approximately 4 technicians perform the DST reading.

In DST reading the resistance or sensitivity of mycobacterium tuberculosis against each drug is examined. First we check the sensitivity of control strain followed by two plain slopes. Finally we check the drug containing slopes. For the control slope all concentrations are checked. But for test slope, only last three concentrations are checked. Finally the result of DST is entered in the DST register.

In the MIC method 'growth' is defined as the presence of 20 colonies or more. As each slope is examined, we record the results as given in Fig 30.

Grade	Result
3+	Confluent growth
2+	Innumerable colonies (>100 colonies)
1+	20-100 colonies
1-19	Actual number of colonies

Figure 30: DST Grading (MIC)

If the drug-free control slope yields 100 colonies or less, we repeat the test for the control slope. However, if the control slope shows no growth or is contaminated, repeat the test from the original positive culture or from an alternate culture from the same patient, if available. Record the lowest concentration of the drug inhibiting growth (MIC).

Drugs	Resistant	Doubtful
Isoniazid	MIC > 5	MIC = 1*
Rifampicin	MIC > 128	
Ethambutol	MIC > 8	MIC = 4*
Ofloxacin	MIC > 8	
Kanamycin	MIC > 64	
Ethionamide	MIC > 114	

* Repeat the test from control slope.

Figure 31: Drug Resistance (MIC)

Fig 31 illustrates the definitions of resistance in MIC method.

Interpretation (Streptomycin) : Record the lowest concentration of drug inhibiting growth (MIC). Divide the MIC of the test strain by the MIC of the standard strain, H37Rv to obtain the Resistance Ratio (RR). Both MIC and RR is performed only for Streptomycin. For all other drugs only MIC is performed.

Definition of resistance:

- Sensitive : RR of 2 or less
- Doubtful* : RR of 4
- Resistant : RR of 8 or more

In case of a doubtful result the test will be repeated.

Interpretation of Tests PST – Method: Interpretation of all tests is based on the 42-day readings. However, if a strain shows clear-cut resistance based on the 28-day reading, no

further reading is needed and the report may be sent as such. Strains that are susceptible at 28 days must be read again at 42 days and the report is based on the later reading only. For each strain, express the number of organisms resistant to each drug concentration as a percentage of the number of organisms growing on the drug-free slope. Make the selection of slopes for estimating the growth on the drug-free and drug containing media in the following order of preference:

1. 20-70 colonies

2. 5–19 colonies

More than 70 colonies

Fig 32 describes the definitions of resistance in PST method.

Drug	Concentration (mg/l)	Proportion
Dihydro Streptomycin	4	1% or more
Isoniazid	0. 2	
Rifampicin	40	
Ethambutol	2	

Figure 32: Drug Resistance (PST)

Enter the Niacin result and growth in PNB in the culture volume. The repeat of test is needed on the following cases;

- If Niacin & PNB both negative then repeat both.
- If Niacin & PNB both positive then repeat both.
- If Niacin negative & PNB positive after repeat then write DNR (Do not Record) in the DST volume book.

The PNB and Niacin (confirmation tests)reporting is as given in fig 3

PNB	Niacin	Report
+	Neg	UMB

Neg	+	Typical
Neg	Neg	Give it for HPLC
+	+	Give it for HPLC

Figure 33: Confirmation Reporting

The technicians make entries in the DST register such as the details of the lab numbers along with the patient's name (from the culture register), drugs for which the DST is setup and their batch numbers. Fig 34 shows the format of DST register. We enter the date of DST setup for the respective lab numbers in the culture register along with the page numbers in the DST register in which the results are to be entered. If the lab numbers are from repeat DST, enter the details of the date of setup and score against the respective numbers in the Repeat DST note book (Fig 35). Repeat is performed whenever any discrepancy happened for the drug containing slope. The result of DST is given to the Statistics department.

Page:- 1 (Regimen-1)

Name	Date:				Drug free slopes result	Batch No.: S							
	Study No.	T. No.	Culture No.	Drugs		2	4	8	16	32	64	MIC	RR
			$H_{37}RV$	SHRE									

Batch No.: H							Batch No.: R						
0.025	0.05	0.1	0.2	1	5	MIC	4	8	16	32	64	128	MIC

Batch No.: E						PNB	Niacin	To Repeat	Remark
0.5	1	2	4	8	MIC				

Page:-2 (Regimen-2)

Name	Date:				Drug free slopes result	Batch No.: H					
	Study No.	T. No.	Culture No.	Drugs		0.025	0.05	0.1	0.2	1	5	MIC

			$H_{37}RV$	HREOF								

Batch No.: R							Batch No.: E					
4	8	16	32	64	128	MIC	0.5	1	2	4	8	MIC

Batch No.: OF						PNB	Niacin	To Repeat	Remark
0.5	1	2	4	8	MIC				

Page:- 3 (Regimen-3)

Name	Date:				Drug free slopes result	Batch No.: K						
	Study No.	T. No.	Culture No.	Drugs		2	4	8	16	32	64	MIC
			$H_{37}RV$	KThOF								

Batch No.: Th							Batch No.: OF						PNB	Niacin	To Repeat	Remark
20	28.5	40	57	80	114	MIC	0.5	1	2	4	8	MIC				

Figure 34: DST Register

Date:			
Lab No.	Drug	From original or from drug	Set up

Figure 35: Repeat DST Note Book

3. Reference Architecture of Proposed Bacteriology Laboratory Management System

Figure 36 gives the reference architecture of the proposed system. It consists of seven segments. They are a) Registration b) Lab reception c) Smear & culture set up lab d) Smear reading lab e) DST, ID, Subculture set up lab f) Culture, DST, ID, Subculture reading lab g) Bacteriology server.

In registration segment a unique bar-coded treatment number is assigned to each new patient. When an already registered patient comes the registry clerk scans the bar-coded treatment number from the ID card and continues with subsequent procedures.

Each technician in the following four segments i.e. i) smear & culture set up lab ii) smear reading lab iii) DST, ID, Subculture set up lab iv) Culture, DST, ID, subculture reading lab, will be guided by a Netbook/tablet PC for each of his operations using visual icon based commands. The bar code readers are then used whenever the lab number need to be inputted to the system. Each segment consists of around two barcode printers, two barcode readers, and two Nttbook/tablet PCs. The complete lab will be Wi-Fi enabled so that the information entered by the technician will be stored in a local server system within the lab. It will be moved to the central server at periodic intervals.

The lab reception segment provides a unique identification for each sample in the form of bar-coded lab numbers. Then these barcode labels are pasted on the specimen containers.

The final segment is the central server. The central repository is a unified database of all collected data, which includes patient details, daily filled various test results, etc. This central database is intended to offer a better overview of data and easier follow up of patients. In order to prevent accidental loss of data, copies of backup of the database are created at regular intervals. It will be possible for clinicians with necessary access permissions to access the database from anywhere and create reports based on various query outputs. The access to central database can be restricted to selected personnel or group of personnel based on access privileges set up for this purpose.

Finally, all the details regarding a patient will be available in the doctor’s desk for the analysis and further treatment. It will eliminate the turnaround time for obtaining various test results from current records.

3.1 Application Modules of Reference Design

The Bacteriology management System of reference design is formed out of a number of co-operating, but independent software modules that runs over the light weight net-book/tablet platforms. Table 1 gives an overview of these modules. Remaining subsections briefly describe the functionality of these modules.

It is assumed that each technician can have a Net-book / tablet PC and he can login to the system by providing his username and password. The remaining subsections briefly describe the functionality of these proposed modules.

3.1.1 Login

This is the standard module by which the technician enters the system by giving a user name and password. For added protection, the system will maintain the MAC address of the network cards known to it and login from these systems only will be allowed.

3.1.2 Registration

A new patient has to register himself at the reception. Here the registry clerk collects the patient's demographic details like name, age, sex, address etc. and enter them to the system. A central treatment number is assigned to a patient for future reference. The treatment number has the format of HHXXXXX where HH is the study center and XXXXX is the 5 digit sequence number. After the completion of registration process a bar-coded treatment number is pasted on the patient ID card and is delivered to the patient for his treatment follow up.

3.1.3 Lab Reception

The capturing of specimen types, collection time, date, name of collector, signature and time of entry into the system are important features that are required to maintain traceability. Once the samples are collected, a unique lab number is generated in the form of barcodes.

The module should have the capability to input the bottle number, T number and Name. The location is selected from a list of predefined locations. The system should automatically generate the lab number and print 4 bar code labels. One of them is used to paste on the sputum card and another two the bottle. The rest are sent along with the sputum card for usage in the smear and culture sections. The data should go into culture selection application.

3.1.4 Smear and staining Set-up

In smear set-up application the smear set-up technician is directed to set-up the smear as per the requirement of the scenario. The barcode sent by the lab reception may be used for setting up the smear. Alternately, a new bar-code may be generated using the bar code printer available in this laboratory. Once the smear is set up, the system monitors the time and can alert the smear reading application to alert the technician that the smear may be ready for reading.

3.1.5 Smear Reading

In smear reading application One reader and a checker have an option for entering the results along with the facility of entering date of examination, technician name and an option for amendment.

The smear and culture reading applications can greatly benefit from a limited word speech recognition add-on that would help in hands-free input of the result of inspection. This is a slightly involved work and may be attempted for integration in the second phase. However, the voice input from the technician may be captured and stored in the data base in the initial phase itself. It will help in identifying the thought process of the technician as he goes through the slides, an information that will be quite useful in cases where the checker differs from the reader.

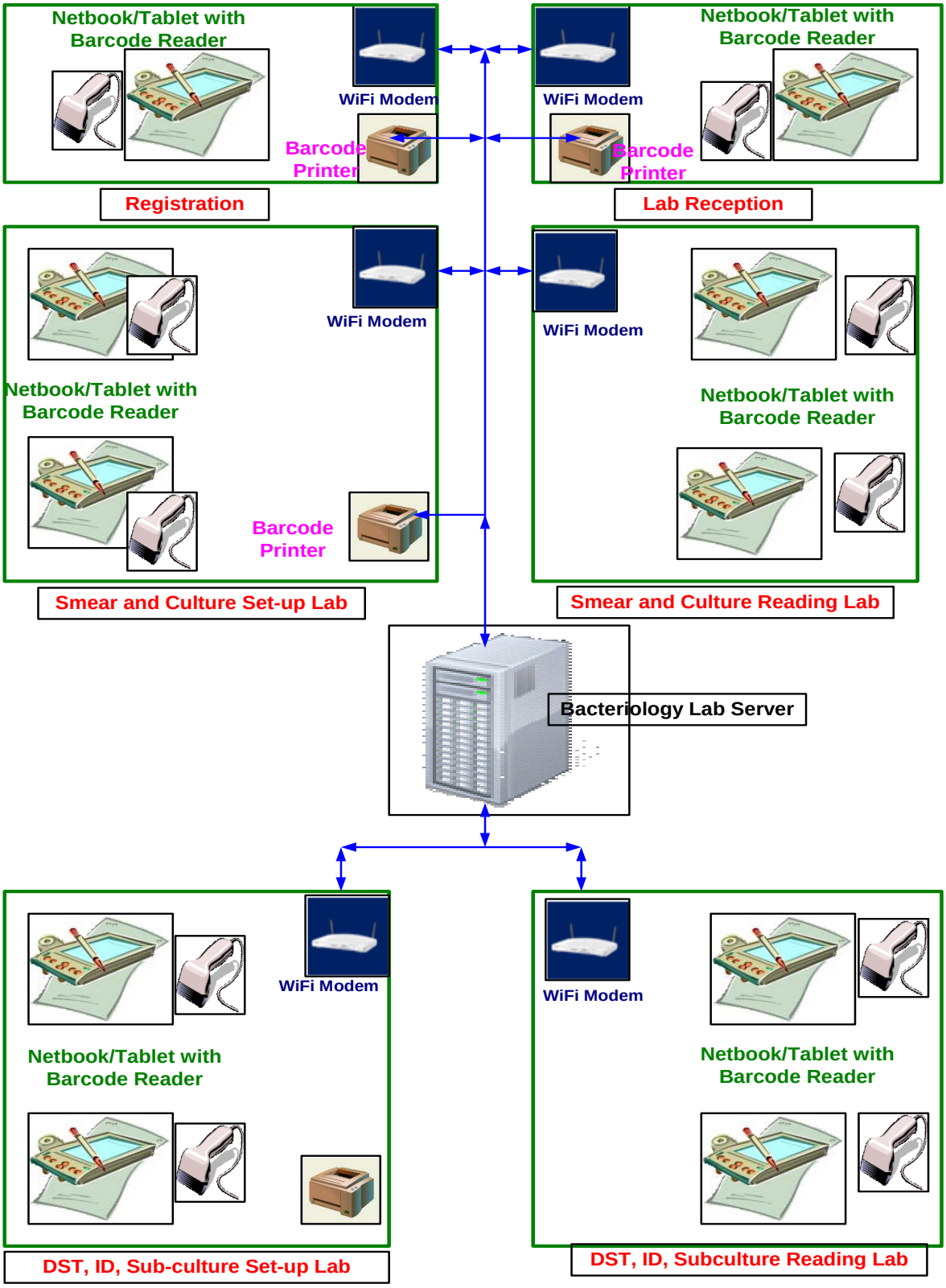


Figure 36: Proposed System Overview with Layout of Equipments

Table 1: Overview of Application Modules

Sl. No.	Module Name	Functions
1	Login	Helps each technician to enter into the system.
2	Registration	Enter the demographic details of a patient and assigns a unique treatment number using barcodes.
3	Lab Reception	Assign unique lab number to each received specimen.
4	Smear Set up	Enter the smear set up information.
5	Smear Reading	Smear reader and checker have the option to enter the results to the corresponding lab number.
6	Culture Set up	Enter the culture set up information.
7	Culture Reading	Culture reader and checker have the option to enter the results to the corresponding lab number.
8	Selection	Enter the DST, ID, sub-culture allocation set based on current culture reading. This is a decision support system for the HoD.
9	Subculture Set up	Enter the sub-culture set up information. Meant for lab technician who set up the sub-culture.
10	Subculture Register	The technician reads the lab number and enters the subculture results.
11	Identification	The technician reads the lab number and enters the ID results.
12	Drug Susceptibility Test - Setup	Enter the DST set up information. Meant for lab technician who set up the DST.

13	DST Register	The technician reads the lab number and enters the DST results.
14	MIS Reporting	Meant for the Statistics department and the higher management. Provides the detailed reports as requested by user.
15	Administration	The administrator has the overall control of the above mentioned applications.

3.1.6 Culture Set-up

This is very similar to smear set-up application, the difference being the work-flow is for culture set-up. The technician is directed to set-up the culture as per the requirement of the scenario. The barcode sent by the lab reception may be used for setting up the culture. Alternately, a new bar-code may be generated using the bar code printer available in this laboratory. Once the culture is set up, the system monitors the time and can alert the culture reading application to alert the technician that the culture is be ready for reading. This will help in identifying cultures that are missed out in reading due to any reason.

3.1.7 Culture Reading

The culture reading application lists the set of lab numbers that are ready for first week reading, second week reading etc. up to 8^{th} week reading. The technician has options for entering the results for 8 weeks and the final result. At the end of this form the technician has opportunity for making amendment if any change occurs. This application has the facility to categorise the lab numbers that are selected for subculture, identification and DST.

3.1.8 Culture Selection : DST, Subculture, ID, Storage at -80 c and Contamination and discard.

The subculture allocation application runs in the Tablet/NetPC of the HoD of Bacteriology laboratory. It allows him to set-up the sub-culture samples based on the results of the currently completed culture reading application. It will list all positive, doubtful and non-usable cases and allows him to decide on the course of action corresponding to sub-culture. This will be in the form of a list box where he can tick in the appropriate option. The ticked options are saved in the data base and are subsequently used in the sub-culture set-up application to ensure that the directions given by the HoD is in fact carried out by the technicians connected with sub-culture set-up.

3.1.9 Sub-Culture Set-up

This is the complementary application of sub-culture allocation. In this, the technician is helped to set up the sub-culture corresponding to the allocated samples. A new bar-code is to be generated using the bar code printer available in this laboratory. Once the sub-culture is set up, the system monitors the time and can alert the sub-culture reading application to alert the technician that the sub-culture is be ready for reading. Two LJ and one PNB is used for subculture.

3.1.10 Sub-Culture Reading

This is very similar to the culture reading application, the only difference being the input is sub-culture samples and therefore the reading logic is different. It incorporates the program logic corresponding to sub-culture recording and allows correct identification based on the observed results specified by the technician, thereby eliminating chances of manual errors. A culture is selected for Niacin

3.1.11 Identification

The identification application provides the facility of entering the, culture morphology, smear morphology culture set up date and confirmation test (Niacin and PNB) results into the system. If any change occurs in results the technician has an option to amend them.

3.1.12 DST Set-up

This is similar to the sub-culture set-up application. In this, the technician is helped to set up the DST corresponding to the allocated samples from culture selection. A new bar-code is to be generated using the bar code printer available in this laboratory and pasted on the first two tubes (Plain LJ). Once the DST is set up, the system monitors the time and can alert the DST register application to alert the technician that the DST is be ready for reading. One LJ tube goes for niacin after the reading.

3.1.13 DST Register

This is very similar to the culture reading application, the only difference being the input is DST samples and therefore the reading logic is different. It incorporates the program logic corresponding to DST recording and allows correct identification based on the observed results specified by the technician, thereby eliminating chances of manual errors.

The DST application facilitates the technician to input the DST set up time and DST results for different concentrations. This application also has an option for making amendments.

NIACIN set up : This application opens from DST, subculture and identification module.

Niacin Reading : Positive or Negative and the results should be reflected in respective module (DST, Subculture and ID)

3.1.14 MIS Reporting

Database administrator is the only one who is able to access directly to the central database and edit the data.

At the end of every section, the user has the opportunity to digitally sign the section, by filling/entering his/her password in the appropriate signature-input field. By signing a section, the corresponding forms are locked and all further modifications are disabled. In this way, the user confirms that the data in the forms are complete and valid.

The MIS reporting application provides all facilities by which any type of report can be provided to an authorised user. The authorisation will be normally set up by the Statistics department, corresponding to the patient ID or groups of patient Ids and is strictly enforced by the system. The access history into the data base by different users also will be monitored and events of access violation will be reported to the highest level. This will ensure reduction in such attempts.

3.1.15 System administration

This is a privileged task that takes care of creation of user accounts, taking back-ups, tuning system parameters, etc. The system will be set up in such a manner that administrative password is not sufficient to access encrypted data base fields. Only the person who encrypted them will be able to decrypt such fields.

The system administration takes care of regular monitoring and tuning of the system. He provides user access and manages the integrity of the total system.

3.2 Re-Engineered Workflow

The following subsections provide the re-engineered workflow at the various sections described in section 2.

3.2.1 Registration

During registration the registry clerk captures the patient data and stores it in the tablet/Netbook. A registered patient has to be identified by unique treatment number. The patient is also given a patient identification card in which the bar coded treatment number is pasted.

At the reception, a bottle is given to the patient and the bottle number is recorded in to the tablet by the concerned staff. Also, he mentions the type of specimen that is clinical or home sample.

3.2.2 Lab Reception

Submission sputum sample at lab reception will follow the same workflow as before, as far as the patient is concerned. On submission, the technician in the lab reception reads the bar-coded treatment number from the patient id card and it leads to the patient profile, and checks the authenticity of the bottle number. Then, he can assign lab numbers to each sample and the computer generated barcode labels are pasted on to the bottles. Same procedure is followed for sending bottles to the lab as mentioned in section 2.

3.2.3 Smear Test

Smear set up procedure is same as existing. For the identification of smear slides, bar coded labels are duplicated and pasted on them. The technician then input the necessary information regarding smear set up in to the system.

The smear reading technician scans each bar coded lab number and examines the slides. Then he enters corresponding result to the tablet/Net PC. Note that the entire lab is Wi-Fi enabled. Initially these results are stored in a local server system. It will be moved to the central server system periodically.

3.2.4 Culture Test

Existing procedure is followed for the culture set up. For the two culture slopes the barcode labels are duplicated. After completing the minimum incubation period, the prepared culture samples are ready for reading. The technician who is responsible for culture reading examines the cultures and makes entry into the tablet by scanning the barcode labels. Based on the culture results all the subsequent lab tests are performed.

3.2.5 Drug Susceptibility Test and Confirmation Tests

For the positive cultures the drug tests is performed. For the setting up of drug containing slopes, duplication of bar-coded lab numbers is essential. At the time of examination the technician scans the barcodes and then he can make necessary entries to the tablet PC. The same procedure is followed to the confirmation tests.

3.2.6 Identification and Subculture

Identification and subculture tests are performed for query positive culture slopes. Here also duplication of barcodes is needed. The test results are entered to the tablet by scanning the barcode labels.

3.2.7 Result Verification at Statistics

All the test results are immediately available on the Tablet/Net PC with the statisticians. If they notice any error then they can inform about it to the concerned technicians, by a sending an alert message to the tablet PC of the technician as well as the head of Bacteriology department. This will ensure early resolution of errors.

The statistics department will also make a back up copy of patient details in periodic intervals. They may also take paper backup using a printer as a final precaution against possible deletion of electronic records.

3.2.8 Advice by Medical Officer

Finally, all the inputted test results are stored in the central server. Thus the medical officer can view the progress of all laboratory tests on his screen. However, he may be able to see the results only after the statistics department releases it. In cases of emergencies, the director could permit viewing of the result by doctors even before the statistics department has released them. This is an administrative rather than technical matter.

3.3 Requirement Sizing, Bill of Quantifies, and Device Specifications

Table 2 gives the bill of quantities of the hardware items needed to establish the reference design, as indicated in Fig 36.

Table 2 : Location Wise Bill of Quantities of Hardware Items

Sno	Location	Item	Quantity
1	Registration	Tablet/NetPC	1
		Barcode Reader	1
		WiFi Modem	1
		Barcode Printer	1
2	Lab Reception	Tablet/NetPC	1
		Barcode Reader	1
		WiFi Modem	1

		Barcode Printer	1
3	Smear and Culture Set-up Lab	Tablet/NetPC	3
		Barcode Reader	3
		WiFi Modem	1
		Barcode Printer	1
4	Smear Reading lab	Tablet/NetPC	2
		Barcode Reader	2
		WiFi Modem	1
5	DST, ID, Sub-culture setup lab	Tablet/NetPC	3
		Barcode Reader	3
		WiFi Modem	1
		Barcode Printer	1
6	DST Culture, ID, Sub-culture reading lab	Tablet/NetPC	3
		Barcode Reader	3
		WiFi Modem	1
7	Server Room	Work station	1
		Printer	1
		On-line UPS	1

Table 3 gives the consolidated BoQ of hardware items with representative specification.

Table 3 : Consolidated Bill of Quantities of Hardware Items

Sno	Item	Representative Specification	Quantity
1	Work Station	High end PC with 4 GB memory, 500 GB or better of secondary storage split into two drives, 15” monitor, WiFi modem adapter, and standard peripherals	1
2	UPS	On-line UPS 1KVA capacity with battery back-up for one hour	1
3	Printer	Laser printer, b/w, medium duty, with 2 spare cartridges	1
4	Tablet or Net PC	10” Tablet PC, high end, with good screen resolution running Android OS version 4.1 or better or 10.5” Net PC of standard specification	13

5	Bar Code Printer	Medium duty with interfacing software for connecting to USB of Tablet/NetPC	4

6	Bar Code Reader	Standard with software for connecting to USB of Tablet/NetPC	13
7	WiFi modem	Standard	6
TOTAL			**35**

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3.4 Other conditions

- The job is to be undertaken on Turn-key basis at site. The bidder will be responsible for procurement of all hardware, integrating them into the working system, installing the system at site, making it operational, providing training to the technicians, providing stationary for one year, and providing one year of comprehensive warranty support for one year.

- The bidder should be willing to give the Annual Maintenance Contract for the next five years, on completion of the above comprehensive warranty support. The amount for this is fixed as 8% of contract value for first year, 10% for second, 12% for third, 14% for fourth and 16% for fifth year. The AMC should cover the hardware, software and operational aspects.

- The reference design given in this Annexure is the property of NIRT. The bidder cannot claim any IP rights on this design. The IP rights of **the** Software, Hardware, or SYSTEM individually developed by the bidder under this contract shall rest with the bidder. The IPR of the Software, Hardware, or SYSTEM jointly developed by the bidder and NIRT, if any, shall be held jointly by the parties. Each party shall ensure that there are no infringements on the IPR of either party or of third parties. Both parties agree that **no information of any kind** provided for performance of or generated out of this project **shall be transferred to third parties without prior written permission from the other party.**

End of Annexure A

Annexure-B

Format of Technical Proposal

1. Overview of Organization

This section should give the overview of the organization from its inception till now with special emphasis on its core competence that is of relevance to the current project.

2. Relevant Experience

This section should give the overview of the relevant experience in handling similar projects. Try to restrict this to a few pages. In case there are many projects, briefly describe upto three of them and give a table giving salient features of others.

3. Overview of Technical Proposal

This section should give the overview of the technical proposal that should provide the system overview with list of equipments in each room indicated in Fig 36 of Annexure A, their proposed interconnection, and the list of software modules to be developed. The bidder is free to use the reference design given in section 3 of Annexure A or change it based on his experience. In case of changed design, complete details are to be included.

4. Consolidated Bill of Quantities of Hardware Items

This section should give the complete details of the hardware items proposed to be installed including make, model, quantities, and main specifications. The details are needed for all purchased out hardware and third party application software.

5. Implementation Team

This section should give the overview of the implementation team that would be responsible for implementation of the project at site. The team structure, the qualification and experience of the team lead and supporting members, along with their reporting structure should be brought out in this section.

6. Implementation Plan

This section should give the overview of the implementation plan in the form of a GANTT chart or a Bar chart of sub activities (including procurement, software development, setting to works,

system installation, trials, operationalisation, user training, hand-over, handholding, etc.), their duration, project milestones, and linkages. Each of the sub activities are to be described briefly to bring out its scope in clear terms.

7. Documentation

This section should give the overview of the documentation that will be provided to NIRT as part of this project. This should include the full documentation of the third party hardware and software items procured including the licences for the same. It should additionally include the user manual for the complete system with separate sections for each user location and/or user type. The comprehensive list of documents to be supplied along with proposed time of submission of same is to be a part of this section.

8. Strategy for Change Management

This section should give the overview of the proposed strategy for change management for current manual system to the proposed automated system. It should indicate the plan for parallel run if any, its duration, methodology, and handling of additional work during this period.

9. Strategy for Training and Hand-holding

This section should give the overview of the proposed strategy for training and hand-holding of the users in NIRT for the proposed automated system. Training would be needed at the levels of technicians, operators, analysts, doctors, and the higher management functionaries. The strategy should indicate the training and hand-holding plan with start dates, durations and the proposed method of training for each user group.

10. Strategy for Upgradation, After-sales support and AMC

This section should give the overview of the proposed strategy for upgradation of the system, after-sales support and AMC. The first should indicate the process for adding additional systems in case the same is requested by NIRT. It should also indicate the process for adding new functionality or modifying existing functionality in software, post operationalisation phase. The second should indicate the proposed plan for fixing any observed bugs, and/or upgrading the third party application software in case these become necessary. The last item should indicate how the bidder proposes to provide AMC support.

11. Deviations from Tender Specifications if Any

This section should give the deviations from the tender specifications in clear terms. In case there are no deviations, the same is to be indicated as “NIL”.

12.List of Enclosures

This section should give a table with columns as SNo, Item, and Number of Pages listing all enclosures attached with the technical bid.

Annexure-C

Performa on Pre-Qualification

General Information						
1	Name of Firm					
2	Legal Status					
3	Established on					
4	Sphere of Operation					
5	Number of employees	Total		In Chennai Unit		
Experience						
6	Details of experience in projects in connected fields (Refer Annexure A)					
6(a)	Number of projects					
6(b)	Total turn-over from them					
6(c)	Title of Project 1					
6(d)	Value of Project1					
6(e)	Customer for project 1					
6(f)	Name, designation and phone number of customer person for reference by NIRT					
6(g)	Brief description of project 1 (less than 300 words)					
6(h)	Title of Project 2					
6(i)	Value of Project2					
6(j)	Customer for project 2					
6(k)	Name, designation and phone number of customer person for reference by NIRT					
6(l)	Brief description of project 2 (less than 300 words)					
Turn-over for Last three years						
7(a)	2012-2013					
7(b)	2011-2012					
7(c)	2010-2011					
Registration numbers						
8(a)	PAN					
8(b)	TIN					
8(c)	Service Tax					
8(d)	VAT					
8(e)	Others (Specify)					

Annexure-D

Format of Commercial Proposal

1. **Tender Number:**
2. **Date of Opening:**
3. **Consolidated Bill of Quantities of Hardware Items**

Sno	Item	Make & Model	Specification	Quantity
1	Work Station			
2	UPS			
3	Printer			
4	Tablet or Net PC			
5	Bar Code Printer			
6	Bar Code Reader			
7	WiFi modem			
8	OS and other system s/w licences (Specify)			
9	Other third party s/w (Specify)			
10	Others (Specify)			
TOTAL				

4. **FINANCIAL SUMMARY IN LAKHS OF RUPEES**

Sn	Item	Qnty	Total Cost	Tax %	Tax Amount	Total
1	Supply of items as per 3 above	lot				
2	Development of Application Software	lot				
3	System Integration	lot				
4	Training and documentation	lot				
5	Cost towards Operationalisation	lot				
6	Warranty support for first year	lot				
7	Other items (specify if any)	lot				
Total						
Total Amount in Words in Rupees						

5. TERMS OF PAYMENT

1st Payment:	25% as advance
2nd Payment:	25% on system installation
3rd Payment:	40% on system operationalisation
4th Payment:	10% on completion of warranty

6. DELIVERY SCHEDULE

• Date of Issue of LoI	T_0
• Submission of BGs	T_0 + 0.5 months
• Signing of Contract	T_0 + 1 Month
• System Ready for Integration	T_0 + ___ Months
• First Integrated Trials at site	T_0 + ___ Months
• System Ready for Operational Trials at site	T_0 + ___ Months
• System Refinement completion	T_0 + ___ Months
• System Operational at site	T_0 + ___ Months
• Closure with all Documents	T_0 + ___ Months

7. Annual Maintenance Contract

Annual Maintenance Contract for the next five years, on completion of the closure of the project at the end of one year will be as follows:

- First Year : 8% of contract value
- Second Year: 10% of contract value
- Third Year: 12% of Contract value
- Fourth Year: 14% of Contract Value
- Fifth Year: 16% of Contract Value

The AMC should cover the hardware, software and operational aspects.

8. VALIDITY OF OFFER

This offer is valid till 31.3.2014

Annexure-E

Draft of Contract to be Signed by Winning Contractor

AGREEMENT BETWEEN THE GOVERNMENT OF INDIA, MINISTRY OF HEALTH AND FAMILY WELFARE, NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS AND M/s _____ FOR CONTRACT FOR "SETTING UP OF AUTOMATION SYSTEM IN BACTERIOLOGY LABORATORY ON TURN-KEY BASIS"

CONTRACT No. NIRT/ . . . . . DATED: . . . . . 2013.

PREAMBLE

CONTRACT AGREEMENT FOR **'SETTING UP OF AUTOMATION SYSTEM IN BACTERIOLOGY LABORATORY ON TURN-KEY BASIS' for** a fixed amount Rs.____/- (Rupees _____ only) inclusive of all taxes.

This contract agreement is made and entered into on this day, ... in Chennai, Tamil Nadu between the President of India represented by the Director, Institute for Research in Tuberculosis (NIRT), Chetpet, Chennai – 600031, Ministry of Health and Family welfare, Govt. of India, hereinafter referred to as the "BUYER" (which terms unless excluded by the context, shall be deemed to include his successor in office) on one part, and _____, hereinafter referred to as the "SELLER" (which terms unless expressly indicated by the context shall be deemed to include its successors and its assignee), on the other part.

WHEREAS the Government had invited quotations vide No. _____ dt _____ for **Setting up of Bacteriology Automation System on Turn Key Basis** as per the scope of work attached in Annexure – I of this contract

AND WHEREAS the SELLER had given his quotation No. _____ dt. _____ and in pursuance of a Tender Purchase Committee meeting held on _____, the same has been accepted by the BUYER and Letter of Intent was issued vide _____ dated _____ as per recommendation of the committee.

AND WHEREAS the SELLER has agreed to NIRT that it is in a position to undertake the CONTRACT FOR **Setting up of Bacteriology Automation System on Turn Key Basis** as per detailed technical specification, Scope of work and other details attached in Annexure – I

It is hereby agreed and declared by and between the parties hereof:-

ARTICLE – 1 : SCOPE OF CONTRACT

1.1 The Seller undertakes to sell and to deliver and execution of work to the Buyer and the Buyer undertakes to accept and pay for all the terms and conditions stipulated in this Contract (nomenclature/specification of the equipment/Work/Service) and accompanied

accessories/ Service according to the technical specifications stipulated in the scope of work as per Annexure – I to this contract and the quantities, fixed unit prices and total value, other details as specified in Article – 5 of this contract. The commercial terms and conditions are given in Annexure – IV to this contract and acceptance test procedures are given in Annexure – II to this contract.

1.2 The prices for the delivered goods are quoted as door delivery at NIRT, Chetpet, Chennai as per the delivery schedule mentioned at Article – 10.

The total contract value of the equipment and documentation to be supplied/ provided according to this contract amounts to Rs _____/- (Rupees _____ only) inclusive of all taxes.

1.3 The contractor shall not be entitled to any other additional payment(s) or any other charges on any other account whatsoever unless otherwise expressly provided for in this agreement. The price(s) is inclusive of all Taxes, Duties, Packing, Forwarding, and Freight for the deliverables / Services as per the accepted terms and conditions.

1.4 Any change made by Govt. in percentage of Taxes/ Duties / Statutory levies, shall be applicable for payment to the SELLER at actual, against documentary evidence. Exemption certificates wherever applicable will be issued by Govt. / Director NIRT and request for the same should be accompanied by all required documents.

1.5 This being a fixed price contract, any variation in Consumer Price Index (CPI) will not be taken into account for purpose of this contract.

1.6 Monitoring and Review of the progress of the Project:

A Project Monitoring Committee (PMC) will be constituted by the Government, Director, NIRT to monitor the progress of the project and will be represented by Officials of NIRT and M/s _____.

1.6.1 Responsibility of the PMC will be the following:

(a) To review technical aspects related to design, manufacture and suggest improvements/ modifications and the committee will be authorised to make minor improvements in the specification without cost implications.

(b) To make inspection and review the status of the project and recommend further actions for progressing the work.

(c) Declare completion of milestones.

(d) Recommendation for payments as per Article – 5 of this contract.

1.6.2 The PMC will ordinarily meet once in three months or as and when required if

necessary, at a mutually acceptable venue and date. The committee is to be chaired by the Director, NIRT or nominee of Director and will discuss issues with SELLER on the activities in progress and hurdles if any.

ARTICLE – 2 : CONTRACT EFFECTIVE DATE

2.1 The deliveries, supplies and performance of the services shall commence from the Contract Effective Date (CED) / _____ (the LOI issue date).

2.2 The Buyer and the Seller have to fulfill the following obligations:-
The seller shall furnish the following applicable documents to the buyer for prompt action:- Bank Guarantee(s), Performa invoice in triplicate, Contractor's bill and other applicable documents like Tax / TIN certificate etc.

2.3 The SELLER agrees to bear the stamp paper cost for this contract under the Indian Stamp Act, 1899.

ARTICLE – 3 : ADVANCE BANK GUARANTEE

A Bank Guarantee as per Annexure II for 25% advance payment shall be provided by the Seller for Rs. ____, to enable the Buyer release the advance amount, as indicated in Article-5.

ARTICLE – 4 : PERFORMANCE BANK GUARANTEE

4.1 A Bank Guarantee as per Annexure III for 10 % of contract value as indicated in Article – 5 is to be furnished by the Seller.

4.2 In case any claims or any other contract obligations are outstanding, the SELLER will extend the Bank Guarantee as asked by the BUYER till such time the SELLER settles all claims and completes all contract obligations.

ARTICLE – 5 : PAYMENT TERMS

5.1 The price agreed upon by both parties during the contract negotiation is as follows:

1) 25% advance against Bank Guarantee on submission as given in Appendix II.
2) 25% on system installation at site.
3) 40% on successful system operationalisation at site.
4) 10% on end of one year of warranty period.

5.2 All financial obligations/ liabilities are to be settled only between SELLER and Director, NIRT, Chennai through Accounts Officer, NIRT, Chennai - 600031.

5.3 The SELLER shall not be entitled for any additional payment during the tenure of this contract due to escalation of prize index.

5.4 Payment is released against satisfactory competition of jobs/ acceptance of item(s).

5.5 A pre-receipted bill(s) duly affixed revenue stamp is to be submitted in triplicate by the Seller to Buyer along with all documents, like Proof of despatch, Tax certificates, Contractor's bill in duplicate etc. and the payment shall be made within 30 days from the date of receipt of the item(s)/Bill.

5.5 Bills are to be addressed to the Director, National Institute for Research in Tuberculosis, Mayor Satyamoorthy Road, Chetpet, Chennai – 31, showing all details in bill format duly indicating the TIN / CST No.

5.6 All payments from NIRT shall be made by Accounts Office, through e-payment as per the mandatory data furnished (i.e. Seller's banker Name & address, and Account No & Type, NEFT/IFS Code of bank, MICR code of Bank, PAN Number and contact Numbers , E mail address etc)

5.7 Liquidated Damages will be levied at the rate of 0.5% per week subject to a maximum 5% of the value of incomplete supply/ job for the delay in execution of the job/supply.

5.8 Income tax, as applicable will be deducted at source and the TDS certificate will be issued by paying authority, Accounts Officer, NIRT, Chennai on request.

5.9 Seller's Bank details for e-payment are as follows:

1.	Name of the supplier	
2.	Suppliers Name (As shown in the Bank Account)	
3.	Suppliers Bank Account No.	
4.	Type of Account (SB/CC/CA)	
5.	Name of the bank & Address	
6.	NEFT/IFSC Code of the Bank	
7.	MICR Code of the Bank	
8.	PAN Number	
9.	Contact Telephone No.	
10.	E-mail ID, If any	

ARTICLE – 6 : SPECIFICATION

6.1 The SELLER guarantees to meet the Scope of work as per Annexure – I and Acceptance Test Procedure for system as per Annexure – II.

6.2 The SELLER, in consultation with the BUYER, may carry out technical up gradation alterations in the design and specifications due to change in workflow procedures, or other such reasons. This will, however, not in any way adversely affect the end product. Such changes will be mutually agreed and shall not have any price implications.

ARTICLE – 7 : QUALITY

7.1 In order to carry out inspection at various stages of development / integration / testing of components/ subsystems of system, BUYER may depute their personnel/ reps if required to the software development sites/ assembly site, wherever it may be. The Seller may coordinate for the visit of Buyer's team.

7.2 The SELLER confirms that all hardware items to be supplied under this Contract shall be new and shall incorporate all the latest improvements and modifications thereto.

ARTICLE – 8 : DELIVERY

8.1. The duration of the contract is for a period of 9 months from the date of LOI (--.--.201-). The delivery of the goods shall be completed within first 6 months, and those of all other services by the next 3 months. The stipulated delivery period of the contract in accordance with the schedule lay down as under:-

8.1.1	Date of Issue of LOI (11.07.2011)	: T_0
8.1.2	Signing of contract and submission of BGs	T_0 + 0.5 months
8.1.3	System Ready for Integration	T_0 + ___ Months
8.1.4	First Integrated Trials at site	T_0 + ___ Months
8.1.5	System Ready for Operational Trials at site	T_0 + ___ Months
8.1.6	System Refinement completion	T_0 + ___ Months
8.1.7	System Operational at site	T_0 + ___ Months
8.1.8	Closure with all Documents	T_0 + ___ Months

8.2 The seller shall intimate to the Buyer regarding arrival of item/ consignment with representative or transport by FAX/Mail in advance with all details for clearance/ security arrangement without delay.

8.3 All the consignment will be checked in Security gate office, and the same consignment will also to be entered in Material Management Group for receipt confirmation and

further action.

8.4 Final inspection/ installation/ commissioning & acceptance to be carried out by the USER Group of NIRT.

8.5 All the expenses including labor resources incurring in connection with dispatch/ delivery/demurrage will be borne by the SELLER.

ARTICLE – 9 : LIQUIDATED DAMAGES

In the event of the SELLER's failure to supply the stores/goods/Service and conduct trials, installation of equipment, training and operationalisation as per schedule specified in this contract, due to reasons attributable to the SELLER, the BUYER may, at his discretion withhold any payment until the completion of the contract. The BUYER may also deduct from the SELLER as agreed, liquidated damages to the sum of 0.5% of the contract price of the delayed/undelivered stores / services mentioned above for every week of delay or part of a week, subject to the maximum value of the Liquidated Damages being not higher than 5% of the value of delayed stores.

ARTICLE – 10 : WARRANTY

10.1 The SELLER warrants that the goods and services supplied under this contract conform to technical specifications and details prescribed and shall perform according to the said technical specifications.

10.2 The SELLER warrants for a period of one year from the date of successful completion of installation at NIRT or 9 months from the date of operationalisation whichever is later that the systems supplied under this contract and each component used therein shall be free from all types of service defects and failures.

10.3 If within the period of warranty, the goods are reported by the BUYER to have failed to perform as per the specifications, the Seller shall either replace or rectify the same free of charge, within a maximum period of 5 days of notification of such defect /report received by the SELLER, provided that the goods are used and maintained by the BUYER as per instructions contained in the operating manual and instruction. Warranty of the equipment would be extended by such duration of downtime. Record of the down time would be maintained by user in logbook. Spares and Manpower required for warranty repairs shall be provided free of cost by SELLER.

10.4 The SELLER also undertakes to diagnose, service, repair, and/or replace the goods/equipment arising due to accidents, by neglect or misuse by the operator or damage due to transportation of the goods during the warranty period, at the cost mutually agreed to between the BUYER and the SELLER. The SELLER shall intimate the assignable cause of the failures.

10.5 SELLER hereby warrants that necessary service and repair back up during the warranty

period of the equipment shall be provided by the SELLER and the seller will ensure that the downtime is within 5% of the warranty period.

10.6 SELLER shall associate technical personnel / maintenance agency of BUYER during warranty repair / Service and shall also provide the details of complete defects, reasons and remedial actions for defects.

10.7 If the cumulative down time exceeds 15% of the warranty period, the complete equipment shall be replaced free of cost by the SELLER within a stipulated period of 45 days on receipt of the notification from the BUYER by duly modifying and/or upgrading it through design improvement in all Services and Equipments supplied.

10.8 The SELLER will guarantee the Service/ Shelf life of 5 years under the Indian tropical condition.

ARTICLE – 11 : TERMINATION

The Buyer shall have the right to terminate this Contract in part or in full in any of the following cases:-

(a) The delivery of the material is delayed for causes not attributable to Force Majeure for more than 03 months after the scheduled date of delivery.

(b) The SELLER is declared bankrupt or becomes insolvent.

(c) The delivery of material is delayed due to causes for Force Majeure by more than 06 months.

(d) The BUYER has noticed that the SELLER has utilised the services of any Person / Agent in getting this contract and paid any commission to such individual /company etc.

(e) As per decision of Arbitration Tribunal (Article - 13).

ARTICLE – 12 : LAW

The present contract shall be considered and made in accordance to the laws of Republic of India. This contract shall be governed by and interpreted in accordance with the laws of the Republic of India.

ARTICLE – 13 : ARBITRATION

In the event of any dispute or difference arising out of or in connection with this CONTRACT, the same shall be settled amicably by mutual consultation or through the good offices of the Director General, ICMR. If such resolution is not possible, then the unresolved dispute or

difference shall be referred to the sole arbitrator appointed with the consent of both parties; failing which to the Arbitration tribunal consisting of one arbitrator appointed by each party and one umpire appointed by the two nominated arbitrators.

The Arbitration shall be in India in accordance with the rules and procedures of the Arbitration and Conciliation Act 1996 and any enactment thereof. The decision of the Arbitrator(s) shall be final and binding upon the PARTIES and the expenses of the arbitration shall be paid as may be determined by the Arbitrator(s).

ARTICLE – 14 : FORCE MAJEURE

14.1 Should any Force Majeure circumstances arise, each of the contracting party shall be excused for the non-fulfillment or for the delayed fulfillment of any of its contractual obligations, if the affected party informs in a written form to the other party within (30 days) of its occurrence.

14.2 Force Majeure shall mean fires, floods, riots, natural disasters or other acts, that are unanticipated or unforeseeable, and not brought about at the instance of, the party claiming to be affected by such event, or which, if anticipated or foreseeable, could not be avoided or provided for, and which has caused the non-performance or delay in performance, such as war, turmoil, strikes, sabotage, explosions, quarantine restriction beyond the control of either party.

14.3 A party claiming Force Majeure shall exercise reasonable diligence to seek to overcome the Force Majeure event and to mitigate the effects thereof on the performance of its obligations under this contract.

ARTICLE – 15 : NON DISCLOSURE OF CONTRACT DOCUMENTS

15.1 Except with the written consent of the BUYER/SELLER, other party shall not disclose the contract or any provision, specification, plan, design, pattern, sample or information thereof to any third party.

15.2 The CONTRACTOR/SELLER shall ensure that all persons employed on any work in connection with this contract have noticed that this applies to them and will continue to apply so even after the termination of or expiry of the contract. These conditions shall also apply to the sub-contractor, if any, of the contractor.

ARTICLE – 16 : NOTICES

Any notice required or permitted by this contract shall be written in English/ Hindi language and may be delivered personally or may be sent by FAX/Mail/Email/ registered letter, prepaid and addressed to the last known address of the party to whom it is sent.

ARTICLE – 17 : PATENTS AND OTHER INTELLECTUAL PROPERTY RIGHTS

17.1 The IP rights of the Software, Hardware, or SYSTEM individually developed by the bidder under this contract shall rest with the bidder. The IPR of the Software, Hardware, or SYSTEM jointly developed by the bidder and NIRT, if any, shall be held jointly by the parties. Each party shall ensure that there are no infringements on the IPR of either party or of third parties. Both parties agree that no information of any kind provided for performance of or generated out of this project shall be transferred to third parties without prior written permission from the other party

17.2 The prices stated in the present Contract shall be deemed to include all amounts payable for the use of patents, copyrights, registered charges, trademarks and payments for any other industrial property rights.

17.3 The seller shall indemnify the Buyer against all claims from a third party at any time on account of the infringement of any or all the rights mentioned in the previous paragraphs, whether such claims arise in respect of manufacture or use. The SELLER shall be responsible for the completion of the supplies including spares, SMTs/STEs technical literature and training/ aggregates irrespective of the fact of infringement of the supplies, of any or all the rights mentioned above.

ARTICLE – 18 : AMENDMENTS

No provision of this contract shall be changed or modified in any way (including this provision) either in whole or in part except by an instrument in writing made after the date of this contract and signed on behalf of both parties and which expressly states to amend this contract.

ARTICLE – 19 : PRODUCT SUPPORT

19.1 The SELLER agrees to provide Product Support for the system for a maximum period of 5 years excluding warranty period after delivery of the System, as per a separate AMC agreement, the AMC rate being 8% for first year and an increase of 2% on subsequent years. These rates may be changed on mutual agreement.

19.2 In the event of any obsolescence during the above mentioned period of product support in respect of any component or sub-system, mutual consultation between the SELLER and BUYER will be undertaken to arrive at an acceptable solution including additional cost, if any.

19.3 Any improvement/ modification/ up gradation being undertaken by Seller or their sub suppliers will be communicated by the SELLER to the BUYER and, if required by the BUYER, these will be carried out by the Seller at BUYER's cost.

ARTICLE – 20 : TRAINING

The SELLER shall provide the following training to the personnel of the BUYER and representative of the Buyer for future periodic maintenance of the system free of charge:

(a) Operator & Maintenance Training to operators and maintainers nominated by Director, NPOL. The SELLER confirms to the BUYER that maintenance training will be imparted to the satisfaction of the BUYER. Training material consisting of illustrated manuals with system details shall be handed over to the trainers prior to commencement of training.

(b) Other training – as mutually agreed

ARTICLE – 21 : Testimonial and signature

The authorised representative of the Seller should be shown to have been so authorised by the Resolution of the Board of Directors of the Company of the Seller or duly authorised by the Memorandum Articles of Association of the Company along with supporting documents for the same.

IN WITNESS WHEREOF, the President of India, has caused the Director, NIRT, Chennai to sign this agreement for and on his behalf and the common seal of the company has been affixed here to and signed by authorised signatory of the Company who has the necessary power of Attorney, to sign this agreement for and on behalf of M/s _____ on this day, month and year first above written.

Signed for and on behalf of President of India **Signed and delivered by**

(FOR *DIRECTOR, NIRT*) (M/s ___*_____)*

(SEAL)/ BUYER (SEAL)/ SELLER

In the presence of Witnesses:

1. Name & Designation:
Address:

1. Name & Designation:
Address:

2. Name & Designation:
Address:

2. Name & Designation:
Address:

(Legal/Judicial address of both contracting parties)

Annexure – A – Finalized Scope of Work

Annexure – B – Finalized Acceptance Test Procedure

Annexure – C– Performa for Bank Guarantees for Advance and Contract Performance

Annexure – D – Other Commercial Terms and Conditions